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A PRESCRIPTION FOR DRUG LIABILITY AND REGULATION

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I. Introduction

As recent developments with VIOXX®, childhood anti-depressants, and other prescription drugs have shown, two realities accompany prescription drug use. First, every prescription drug is designed to work miracles for some class of patients. Prescription drugs save patients' lives, enhance their well-being, or provide them with hope where hope was lacking. Second, every prescription drug also has potential side effects, unavoidable negative reactions in a limited number of patients that can be very serious for those who experience them. In a system fraught with winners and losers, fashioning the right balance between regulation and liability involves complicated legal, scientific, and moral issues. Given recent attention to the side effects that patients can experience, now is an appropriate time to revisit the way regulation and liability work within the prescription drug market.

As with all regulatory regimes, the United States Food and Drug Administration (FDA) manages public risk by issuing forward-looking regulations that impose "prescriptive controls on risk-creating conduct

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*before*¹ potential injury can occur. What makes the FDA different from other federal agencies is that it must approve the risk-benefit analysis for each product it regulates; each drug must be individually approved before a drug company can make, market, or sell the drug.² This drug-by-drug national risk strategy defines the class of patients who are most likely to benefit from a particular drug and assures that doctors are armed with warnings and instructions so they can have a science-based understanding of the known potential risks that each drug can pose. A doctor then assesses a patient's personal risks and decides whether to issue that patient a prescription for a specific drug.

Liability, on the other hand, is a backwards-looking compensation and enforcement mechanism designed to manage private risks. It looks at an individual incident and requires a culpable party to compensate a person it injures *after* the individual injury occurs, thereby providing strong incentives "to control risky behavior in order to avoid or reduce future liability."³

Liability falls short in the prescription drug context, because, as the American Law Institute's *Reporters' Study (Reporters' Study)* has pointed out, "the tort system is ill-equipped to handle" public risks, particularly in cases requiring "specialized experience in assessing risks and control measures."⁴ In these situations, liability works best when it complements the federal regulatory regime by requiring companies to pay compensation when they cause harm by operating outside of its regulatory structure.

This article discusses the central issue of how liability works when a prescription drug manufacturer fully complies with the FDA's exacting regulation by selling, marketing, and labeling prescription drugs with specific FDA approval, yet, because of the nature of prescription drugs, a certain percentage of patients experience significant foreseen and unforeseen side effects. In these situations, jurists have generally taken one of two paths. Some judges, driven by compassion for a plaintiff or their own sense of "justice," reach their own determination that the alleged side effect is more serious than the drug's potential benefit and allow the plaintiff to pursue compensation by claiming that the drug has a design or a failure to warn

1. 2 AM. LAW INST., ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY: REPORTERS' STUDY 83 (1991) [hereinafter REPORTERS' STUDY] (stating that the regulatory agencies use their expertise to "determine what risks to control, the level of control, and often the means of control").

2. See 21 U.S.C. § 355(a) (2000) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with the Food and Drug Administration] is effective with respect to such drug.").

3. REPORTERS' STUDY, *supra* note 1, at 83.

4. *Id.* at 87.

defect.⁵ Other judges, adhering to the fundamental principles of tort law, have concluded that there can be no design or warning defect when the FDA has approved a drug's specific design and warnings.⁶ These jurists require the manufacturer to have committed an objective wrongful act in order for there to be a basis for liability.⁷ The drafters of both the *Restatement (Second) of Torts* and *Restatement of Torts, Third* have determined that the latter path achieves a more accurate and desirable litigation and public policy outcome.⁸

Part II of this article reviews the development and application of the federal regulatory scheme that controls the prescription drug market. Part III addresses the body of law that has been built over the last half century to complement this regulatory regime. Part IV discusses the appropriate liability regime for prescription drugs in this country. Part V examines the key public policy issues that this liability regime raises. Part VI explains the choices available to courts for implementing this liability regime. Part VII raises causation issues that could undermine rational liability laws. Part VIII briefly concludes the article.

II. Federal Regulation of the Prescription Drug Market

A. Development of FDA Authority to Regulate Prescription Drugs

Until the early twentieth century, the federal government generally left the regulation of medicine and public health to the states.⁹ As a result, drugs were generally unregulated, thus, leaving many ineffective and potentially harmful drugs on the market.¹⁰ Individuals often made their own choices as to which

5. See, e.g., *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 840 (Neb. 2000) (holding that the plaintiff could pursue a design defect claim against the makers of Accutane, a prescription acne medication, and stating that comment k will only apply to prescription drugs on a case by case basis and that, among other factors, the court will consider whether the drug's "benefits justify its risks").

6. See, e.g., *Grundberg v. Upjohn Co.*, 813 P.2d 89, 90 (Utah 1991) ("We hold that a drug approved by the [FDA], properly prepared, compounded, packaged, and distributed, cannot as a matter of law be 'defective' in the absence of proof of inaccurate, incomplete, misleading, or fraudulent information furnished by the manufacturer in connection with FDA approval.").

7. See, e.g., *id.*; *Brown v. Superior Court*, 751 P.2d 470, 482-83 (Cal. 1988).

8. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) [hereinafter RESTATEMENT (SECOND)]; RESTATEMENT OF TORTS, THIRD: PRODUCTS LIABILITY § 6 (1998) [hereinafter RESTATEMENT THIRD].

9. See John P. Swann, U.S. Food & Drug Admin., History of the FDA, at <http://www.fda.gov/oc/history/historyoffda/default.htm> (last visited Sept. 28, 2005) (adapting sections from A HISTORICAL GUIDE TO THE U.S. GOVERNMENT (George T. Kurian ed., 1998)).

10. States' treatment of drugs varied widely:

States exercised the principal control over domestically produced and distributed foods and drugs in the 19th century, control that was markedly inconsistent from

drugs to take, as relatively few doctors existed at the time to recommend medications.

The federal government began its effort to standardize drug monitoring and analytical research in 1902, when the Chief Chemist of the Department of Agriculture's Bureau of Chemistry formed the Drug Laboratory; it was a one-man operation with half a desk.¹¹ A few years later, Congress passed the Pure Food and Drugs Act of 1906,¹² which laid the foundation for modern food and drug law by prohibiting the distribution of mislabeled or adulterated drugs and food in interstate commerce.¹³ In 1912, Congress strengthened the law by prohibiting false and fraudulent claims of therapeutic value,¹⁴ and in 1930, it formed the Federal Food and Drug Administration as part of the Bureau of Chemistry.¹⁵

In 1937, a public health disaster provided the impetus for a tidal shift in federal drug oversight.¹⁶ A well-established pharmaceutical company, Massengill, began selling Elixir Sulfanilamide as treatment for diseases, including strep throat and gonorrhea.¹⁷ The product, which was previously sold as a tablet or in powder form, was manufactured in liquid form in order

state to state. . . . Federal authority was limited mostly to imported foods and drugs. Adulteration and misbranding of foods and drugs had long been a fixture in the American cultural landscape, though the egregiousness of the problems seemed to have increased by the late 19th century (or at least they became more identifiable).

Id.

11. See Donna Hamilton, U.S. Food & Drug Admin., A Brief History of the Center for Drug Evaluation and Research, at <http://www.fda.gov/cder/about/history/Histext.htm> (last visited Sept. 28, 2005).

12. Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040.

13. See Swann, *supra* note 9, at <http://www.fda.gov/oc/history/historyoffda/section1.html>.

14. Shirley Amendment, Pub. L. No. 62-301, 37 Stat. 416 (1912). Congress enacted this amendment after the Supreme Court of the United States ruled that the Division did not have the authority to seize a product that falsely claimed it could treat cancer. See Swann, *supra* note 9, at <http://www.fda.gov/oc/history/historyoffda/section2.html>.

15. U.S. Food & Drug Admin., *FDA Backgrounder: Milestones in U.S. Food and Drug Law History* (Aug. 2005), at <http://www.fda.gov/opacom/backgrounders/miles.html> [hereinafter *FDA Backgrounder*]. The FDA was transferred from the Department of Agriculture to the Federal Security Agency, the predecessor to the Department of Health, Education, and Welfare, and later to the Department of Health and Human Services. *Id.*

16. See Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER, June 1981, available at <http://www.fda.gov/oc/history/elixir.html>.

17. See Paul M. Wax, *Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act*, 122 ANNALS INTERNAL MED. 456, 458 (1995), available at <http://www.annals.org/cgi/content/full/122/6/456>.

to satisfy popular demand by using diethylene glycol as a medium.¹⁸ Massengill did not realize that diethylene glycol was a deadly chemical known today as antifreeze. The drug killed 107 people — mostly children — before the product was recalled.¹⁹ Because Massengill was not required by the 1906 law to test the safety of the product before marketing it, the FDA could only prosecute the tragedy as a case of mislabeling, as Massengill advertised the drug as an elixir, even though it contained no alcohol.²⁰

Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 to require a manufacturer of a “new drug” to test the product and notify the FDA before bringing the new drug to market.²¹ This law, for the first time, required companies to prove the safety of new drugs before placing them into interstate commerce.²² The FDCA also established the requirement of adequate labeling²³ and began distinguishing between products that required a physician’s prescription and those that could be adequately labeled for self-medication.²⁴

In 1962, a public health tragedy involving thalidomide, a treatment for morning sickness that resulted in stillbirths and birth defects, led Congress to “fundamentally restructure[] the way in which the FDA regulated new medicines, transforming a system of premarket notification into one that requires individual premarket approval of the safety and effectiveness of every new drug.”²⁵ Specifically, the 1962 Act gave the FDA responsibility for

18. See Ballentine, *supra* note 16.

19. See *id.* (noting that Harold Cole Watkins, the chemist responsible for developing the drug, committed suicide); *FDA Backgrounder*, *supra* note 15.

20. Ballentine, *supra* note 16.

21. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-399 (2000)).

22. 21 U.S.C. § 355. The 1938 law, while requiring manufacturers to prove the safety of a drug to the FDA before marketing, did not require an evaluation of its effectiveness.

23. See *id.* (stating that a drug would be considered misbranded if its label was “false or misleading in any particular”).

24. See Michael I. Krauss, *Loosening the FDA’s Drug Certification Monopoly: Implications for Tort Law and Consumer Welfare*, 4 GEO. MASON L. REV. 457, 461 (1996) (stating that the Act included a provision that allowed for discretionary exemptions from labeling requirements, which the FDA interpreted as providing it with the authority to create “a category of ‘ethical drugs’ that could henceforth be sold only by prescription”). In 1951, the Durham-Humphrey Amendment clarified the legal distinction between prescription and nonprescription drugs. Ch. 578, §§ 1-2, 65 Stat. 648, 648-49 (codified as amended at 21 U.S.C. §§ 333, 353 (2000)).

25. PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW CASES AND MATERIALS* 13 (2d ed. 1991) (observing the role of the FDA in preventing the outbreak of thalidomide side effects that occurred in Europe from occurring in the United States); see also Jeffrey E. Shuren, *The Modern Regulatory Administrative State: A Response to Changing Circumstances*, 38 HARV. J. ON LEGIS. 291, 301-03 (2001) (stating that the 1962 Act changed

regulating clinical testing of new drugs, inspecting drug manufacturing facilities, promulgating good manufacturing practices,²⁶ and requiring manufacturers to report adverse reactions to approved drugs.²⁷ The FDA also was given oversight responsibilities for prescription drug advertising.²⁸ In short, the FDA had gained full responsibility for prescribing “the standards of safety and, in some instances, the standards of performance particular products must meet before they reach the public.”²⁹

Since the 1960s, this framework has remained in place, with Congress making regular improvements as warranted. For example, in response to complaints from patients, doctors, and pharmaceutical companies that the FDA drug approval process was taking too long,³⁰ Congress enacted the Prescription Drug User Fee Act in 1992, which required manufacturers to pay user fees to the Agency for the evaluation of new drugs.³¹ This fee enabled the FDA to hire more reviewers and decreased the wait time for the public to benefit from safe and effective drugs.³² In fact, the staff at the Center for Drug Evaluation and Research (CDER) increased by over fifty percent between 1980 and 2000.³³

the system from pre-market notification to pre-market approval, which effectively “transformed the FDA’s role from a reviewer of data to an active participant in the drug development process”).

26. See Kefauver-Harris Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified at 21 U.S.C. §§ 321-399 (2000)). The FDA had delayed approval of the New Drug Application for thalidomide, but FDA officials had not suspected the drug could cause birth defects. See *FDAREview.org*, The Independent Institute, History of Federal Regulation: 1902-Present, at <http://www.fda.gov/fda/history> (last visited June 25, 2005). The drug, however, was sold in forty-six other countries prior to discovery of its impact, resulting in thousands of newborns with physical deformities. *Id.*

27. See Arthur H. Hayes, Jr., *Food and Drug Regulation After 75 Years*, 246 JAMA 1223, 1224 (1981) (noting that oversight of drug advertising was previously undertaken by the Federal Trade Commission (FTC)).

28. *Id.*

29. Richard A. Merrill, *Risk-Benefit Decisionmaking by the Food and Drug Administration*, 45 GEO. WASH. L. REV. 994 (1977), reprinted in HUTT & MERRILL, *supra* note 25, at 20.

30. See John Henkel, *User Fees to Fund Faster Reviews*, FDA CONSUMER SPECIAL ISSUE, Jan. 1995, available at <http://www.fda.gov/fdac/special/newdrug/userfees.html>.

31. Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (codified at 21 U.S.C. §§ 379g, 379h (2000)).

32. In reauthorizing the Prescription Drug User Fee Act in 1997, Congress found that the Act “substantially reduc[ed] review times” Food and Drug Modernization Act of 1997, § 101, Pub. L. No. 105-115, 111 Stat. 2296, 2298 (1997). Congress once again reauthorized the Act in 2002. See Public Health Security and Bioterrorism Preparedness Response Act of 2002, tit. V, Pub. L. No. 107-188, 116 Stat. 594.

33. See Daniel Carpenter & A. Mark Fendrick, *Accelerating Approval Times for New Drugs in the U.S.*, 15 REG. AFF. J. 411, 412 (2004) (on file with author) (finding that the number

The FDA today “administers the most comprehensive drug regulatory system in the world.”³⁴ Its mission is to optimize the risk-benefit tradeoff by only allowing drugs on the market if they are reasonably safe for their intended class of consumers and setting marketing and warning requirements that companies must adhere to in order to sell their products.³⁵ With a workforce of 9000 people,³⁶ the Agency regulates more than 150,000 drugs and medical devices.³⁷ It also conducts more than 16,000 visits per year to facilities that handle FDA-regulated products in order to inspect manufacturers, to review shipments of imported products, and to examine product samples for signs of contamination.³⁸ CDER, which began as a one-man operation 100 years ago,³⁹ now employs over 1700 medical doctors, toxicologists, pharmacologists, epidemiologists, chemists, and statisticians.⁴⁰

B. The New Drug Approval Process

The New Drug Application (NDA), the hallmark of the FDA approval process, subjects all prescription drug applications to rigorous formal rule-making review. The NDA enables the FDA to balance carefully the risks and benefits of each prescription drug, to understand the inherent risks, and to determine how to craft warnings for allowing each drug to be used safely and effectively.⁴¹ Where a drug needs to be particularly strong, such as with psychological issues leading to depression, schizophrenia or bi-polar disorder, the FDA may be more tolerant of potentially dangerous side effects, because without those drugs, patients may pose a significant threat to themselves and

of CDER employees increased from approximately 1100 in 1980 to 1700 in 2000).

34. Bert W. Rein et al., *Addressing the Conflict: FDA vs. Torts*, PHARM. & MED. DEVICE L. BULL., May 2003, at 1, 1, available at http://www.lawjournalnewsletters.com/pub/ljn_pharm/3_5/news/141453-1.html (paid access only).

35. “A principal focus of the Food and Drug Administration, apart from safety, is efficacy. Since every drug includes some risks, the Food and Drug Administration regards efficacy as essential — if one is to take risks, he or she should obtain the desired result.” Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1142 (1985) [hereinafter Schwartz, *Comment K*].

36. Jan Elicker, U.S. Food & Drug Admin., *An FDA Overview: Protecting Consumers, Protecting Public Health* (Aug. 2004), at <http://www.fda.gov/oc/opacom/fda101/fda101text.html>.

37. U.S. FOOD & DRUG ADMIN., STRATEGIC ACTION PLAN: PROTECTING AND ADVANCING AMERICA’S HEALTH 9 (2003), available at <http://www.fda.gov/oc/mcclellan/FDAstrategicPlan.pdf> [hereinafter FDA STRATEGIC ACTION PLAN].

38. See Elicker, *supra* note 36. The agency also has signed cooperative arrangements with many state governments to increase the number of facilities that are checked. *Id.*

39. See Hamilton, *supra* note 11.

40. See Carpenter & Fendrick, *supra* note 33, at 412.

41. See generally 21 C.F.R. pt. 314 (2005).

others.⁴² For a drug to be approved, the FDA must determine “that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling”⁴³

1. Drug Design

A drug manufacturer starts the approval process by submitting an “Investigational New Drug” (IND) application to the FDA.⁴⁴ The FDA uses its considerable scientific expertise to review the application and the drug manufacturer’s animal testing of the proposed drug during preclinical research.⁴⁵ Only after the FDA approves the IND can a company use the drug in tightly controlled tests with real patients, who agree to participate in the experimental drug program, for gathering data on the drug’s clinical safety and efficacy.⁴⁶ Upon conclusion of those tests, the manufacturer files a New Drug Application (NDA), detailing the chemistry of the drug, clinical data and patient information, its use in children, reports of adverse reactions, and proposed packaging and labeling, as well as any other pertinent manufacturing

42. For example, side effects for prescription drugs that may be prescribed for schizophrenia include Neuroleptic Malignant Syndrome, Tardive Dyskinesia, Diabetes Mellitus, and other potentially severe side effects. See PHYSICIANS’ DESK REFERENCE 2609 (59th ed. 2005) (discussing contraindications, warnings and precautions for Geodon); *id.* at 1742 (for Risperdal); *id.* at 662 (for Seroquel); *id.* at 1899 (for Zyprexa).

43. 21 C.F.R. § 314.105(c). “In fulfilling its mission to monitor and control the safety and efficacy of drugs, the Agency continually walks a razor’s edge between two opposing risks — premature approval of dangerous drugs and undue delay in making safe, effective, and medically useful drugs available to the public.” Steven R. Salbu, *The FDA and Public Access to New Drugs: Appropriate Levels of Scrutiny in the Wake of HIV, AIDS, and the Diet Drug Debacle*, 79 B.U. L. REV. 93, 96 (1999) (citations omitted).

44. See CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., THE CDER HANDBOOK 7 (Mar. 16, 1998), at <http://www.fda.gov/cder/handbook/> [hereinafter CDER HANDBOOK]. Generic drugs can use the Abbreviated New Drug Application (ANDA) if it can be based on the pioneer or “listed” drug’s approval. 21 U.S.C.A. § 355(j) (West 1999 & Supp. 2005). The generic must be the “bioequivalent” of the pioneer drug, have the same active ingredient, route of administration and dosage, and safe inactive ingredients. *Id.* §§ 355(j)(4)(c), (D), (H).

45. See 21 C.F.R. § 312.23. Animal testing is done to determine a drug’s potential effect in human beings by using the drug’s reaction in animals to identify the chemical compounds at work and assess the toxicity of the drug. See *id.*

46. See 21 U.S.C.A. § 355(b)(1); 21 C.F.R. §§ 312.20, 312.21; see also Charles J. Walsh & Alyssa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 905-07 (1996) (discussing the three phases of human trials).

information.⁴⁷ An NDA often spans thousands of pages and describes the impact of the drug in several hundred to several thousand patients.⁴⁸

The CDER's medical officers review the results of the human testing and determine whether the amount of data provided by the manufacturer is sufficient to extrapolate the scientific findings of the test sample to the general population.⁴⁹ They can order additional testing or seek the expertise of independent advisory committees.⁵⁰ Ultimately, this medical team must approve the prescription drug as being safe and effective for public use.⁵¹

2. Warnings and Labels

To comply with FDA regulations, warnings must "portray the drug's safety profile with accuracy, balance, and brevity" to help physicians prescribe drugs in ways that maximize a drug's effectiveness and minimize its risks.⁵² The label must include basic information, such as a description of the drug, identity of its manufacturer, statement of ingredients, and an expiration date.⁵³ The label must provide directions for its intended use in the treatment, prevention, or diagnosis of a disease or condition; this information includes any necessary preparation, dosage (recommended, usual, and maximum dosage), and frequency and duration of use.⁵⁴ A label also must include a description of any "situations in which the drug should not be used because the risk of use clearly

47. See 21 U.S.C.A. § 355(b); 21 C.F.R. §§ 314.50 (providing the required content and format of an NDA), 314.55 (requiring assessment of safety and effectiveness in pediatric subpopulations); see also CDER HANDBOOK, *supra* note 44, at 21.

48. See *Grundberg v. Upjohn Co.*, 813 P.2d 89, 96 (Utah 1991) (detailing the FDA NDA process).

49. See CDER HANDBOOK, *supra* note 44, at 22-23.

50. See *id.* at 23-25. During this process, the manufacturer may submit additional information, as amendments, such as new analysis of previously submitted data or further study to address questions raised during the FDA review. 21 C.F.R. § 314.60; CDER HANDBOOK, *supra* note 44, at 25. FDA investigators may inspect the manufacturer's facilities to verify the accuracy of the practices detailed in the application, to review manufacturing safeguards, and to collect samples for testing. CDER HANDBOOK, *supra* note 44, at 27-28; see also 21 C.F.R. pts. 210, 211 (2005) (providing good manufacturing practices for manufacturing, processing, packing, or holding of drugs).

51. See CDER HANDBOOK, *supra* note 44, at 25.

52. W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1440 (1994) [hereinafter Viscusi, *Deterring Inefficient Litigation*]. See generally 21 C.F.R. pt. 201 (2005) (stating the substantive and stylistic requirements for labels, including that labels and warnings have proper prominence, typeface, and text size).

53. See 21 C.F.R. §§ 201.1, 201.10, 201.17, 201.50, 201.51.

54. See *id.* §§ 201.5, 201.55, 201.57.

outweighs any possible benefit.”⁵⁵ This may include precautionary information regarding any special care needed for the safe and effective use of the drug, such as its use during pregnancy or by children.⁵⁶

Finally, a label must include information on potential side effects, which the FDA breaks down into three categories: (1) “contraindications,” where taking the drug would place a patient under severe risk and the patient should be discouraged from taking the drug; (2) “warnings,” which are serious risks known to occur in some patients; and (3) “precautions,” which are risks that arise less frequently.⁵⁷ The manufacturer also must include on the label the steps that should be taken in the event of an adverse reaction, the potential for dependency or abuse, the signs and symptoms of an overdose, and the means of treatment.⁵⁸ Unless the FDA grants a specific waiver, the manufacturer must include every element of the extensive disclosures in its labeling.⁵⁹

3. Final FDA Approval

The NDA process is complete only when the Division or Office Director signs an approval action letter allowing the manufacturer to market the drug in the United States.⁶⁰ Only eight percent of prospective products submitted to the Agency receive approval and enter the marketplace.⁶¹ The average process for bringing a drug to market takes more than a decade and \$800 million.⁶²

55. *See id.* § 201.57(d).

56. *See id.*

57. *Id.* § 201.57(d)-(f).

58. *Id.* § 201.57(g)-(i).

59. *Id.* § 201.58.

60. CDER HANDBOOK, *supra* note 44, at 25. Statutorily, the FDA must approve or reject a New Drug Application (NDA) within 180 days of filing. 21 U.S.C.A. § 355(c)(1) (West 1999 & Supp. 2005); 21 C.F.R. § 314.100(a). In practice, the time frame is much longer because the FDA does not consider an application “filed” until it includes all the required information. Overall, the NDA approval process usually takes one-and-one-half to two years. *See* Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., Description of Line Chart: New Drug Application Rates for NDAs Received in FY 1993-2002 and Approved Within 36 Months (Apr. 15, 2003), at <http://www.fda.gov/cder/present/MedianAPtime/LifeTables/DescLifeTableN2agg9302.htm>. Products that treat life-threatening conditions may be eligible for accelerated approval. *See* 21 C.F.R. § 314.500.

61. *See* Lester M. Crawford, Acting Commissioner of the FDA, Speech Before the Mayo Alliance for Clinical Trials Conference (Aug. 26, 2004), available at <http://www.fda.gov/oc/speeches/2004/mayo0826.html>. According to the FDA, the eight percent approval rate is a historic low for the product approvals. *Id.*

62. *See* FDA STRATEGIC ACTION PLAN, *supra* note 37, at 10. The price of developing and bringing a new drug to market has increased rapidly over the past decade. *Id.* (noting that the cost has more than doubled over the past decade); *see also* Henry I. Miller, *Failed FDA Reform,*

C. After-Market Responsibilities

The FDA conducts extensive post-market surveillance to assess whether a drug's real-time safety and efficacy results remain consistent with the risk-balancing decisions made during the NDA process.⁶³

This information often comes from epidemiological studies conducted by drug manufacturers, the government, or other entities.⁶⁴ These studies examine whether those who take the drug experience previously unknown side effects or whether the instructions for dosage and duration should be amended to achieve the optimal risk-benefit trade-off.⁶⁵ In addition, drug companies must report all adverse drug reactions, regardless of whether the company or attending physician believes the adverse illness is related to the drug.⁶⁶ Manufacturers also must submit reports on actions taken in response to such adverse drug reactions, as well as any new developments in scientific knowledge on the drug.⁶⁷ This responsibility includes the submission of data from post-marketing reports, studies included in scientific literature, and experiences with the drug in other countries.⁶⁸ The FDA can enforce these reporting requirements through civil and criminal penalties.⁶⁹

Currently, the FDA monitors more than 10,000 drugs on the market and receives more than 400,000 problem reports a year.⁷⁰ Should after-market results indicate that the risk-benefit analysis of the design or warnings are no longer appropriate, the FDA can send warnings to physicians or other health

REGULATION, Summer 1998, at 24, 24 (attributing an increase in cost for new drug development and approval from \$359 million to \$500 million — in pretax 1990 dollars — between 1990 and 1993, and an increase in the time for approval from 8.1 years to 15.2 years since the 1960s to the “FDA’s regulatory zeal”).

63. *See generally* 21 C.F.R. § 314.81.

64. *See id.* § 314.81(b)(2)(vi)(a) (requiring “[p]ublished clinical trials of the drug (or abstracts of them), including clinical trials on safety and effectiveness; clinical trials on new uses; biopharmaceutic, pharmacokinetic, and clinical pharmacology studies; and reports of clinical experience pertinent to safety (for example, epidemiologic studies or analyses of experience in a monitored series of patients) *conducted by or otherwise obtained by the applicant*”) (emphasis added).

65. *See id.* § 314.81.

66. *See id.* § 314.80(b).

67. *See id.* § 314.80(b), (c).

68. *See id.* § 314.80(b).

69. *See* 21 U.S.C. §§ 332-334 (2000).

70. *See* U.S. FOOD & DRUG ADMIN., CONGRESSIONAL JUSTIFICATION: FY 2003 ANNUAL PERFORMANCE PLAN 2.3.1 (2003), *available at* <http://www.fda.gov/ope/fy04plan/2004pp-drugs.html>; Elicker, *supra* note 36, at slide 18.

practitioners, require labeling changes, ask the manufacturer to recall a drug, or withdraw the drug's approval altogether.⁷¹

In late 2004, “[c]riticism of how the FDA monitors after-market drug safety” grew, and the FDA changed its procedures to allow for even tighter controls.⁷² The spark was Merck’s withdrawal of VIOXX, a COX-2 Inhibitor that helped mitigate pain from arthritis and minimize the potential for stomach bleeding, which is a common side effect of some other arthritis medications.⁷³ Studies of after-market results showed that VIOXX taken daily for more than eighteen months could lead to increased risk of heart attack and stroke.⁷⁴ After studying these and other scientific data, an FDA expert advisory panel ultimately voted to allow VIOXX to be marketed in the United States with certain restrictions and heightened warnings.⁷⁵ In addition, there was increased concern about the effect of certain antidepressants on children, as a number of children who had taken these drugs had committed suicide.⁷⁶

Congress held hearings on both of these issues, and the FDA responded by creating a new independent Drug Safety Oversight Board (Board) to monitor

71. See 21 C.F.R. § 200.5 (2005) (“[T]he Food and Drug Administration occasionally [is] required to mail important information about drugs to physicians and others responsible for patient care.”); *id.* § 201.200(a)(2) (“The Food and Drug Administration is . . . initiating administrative actions as necessary to require product and labeling changes.”); 21 C.F.R. § 7.45(a) (2005) (“[t]he Commissioner of Food and Drugs or designee may request a firm to initiate a recall”); 21 U.S.C. § 355(e) (providing withdrawal authority).

72. Lisa Richwine, *FDA to Create New Drug Safety Board*, REUTERS, Feb. 15, 2005, available at http://www.boston.com/business/articles/2005/02/15/fda_to_create_independent_safety_board.

73. See *id.*; Merck & Co., Inc., Patient Product Information, at http://www.vioxx.com/rofecoxib/vioxx/documents/english/vioxx_ppi.pdf (Aug. 2004) (explaining that VIOXX is used to relieve arthritis pain); Marc Kaufman, *FDA Panel Opens Door for Return of Vioxx*, WASH. POST, Feb. 19, 2005, at A1 (noting that VIOXX was designed to avoid gastrointestinal problems that were sometime caused by older painkillers).

74. Press Release, Merck & Co., Inc., Merck Announces Voluntary Worldwide Withdrawal of VIOXX® 1 (Sept. 30, 2004), available at http://www.vioxx.com/vioxx/documents/english/vioxx_press_release.pdf.

75. See Marc Kaufman, *FDA Panel Opens Door for Return of VIOXX*, WASH. POST, Feb. 19, 2005, at A20 (reporting that the thirty-two-member commission banned direct-to-consumer advertising for VIOXX and other COX-2 drugs and required a highlighted black box warning on the bottle label on the risks of heart attacks and strokes).

76. See, e.g., *Hearing Before the H. Subcomm. on Oversight and Investigations*, 108th Cong. (Sept. 23, 2004) (statement of Dr. Robert Temple, Director, Office of Medical Policy, Food and Drug Admin.), available at <http://www.fda.gov/ola/2004/antidepressant0923.html> (“Suicidality, in the context of treating patients with depression and other psychiatric illnesses, has been a genuine concern and a longstanding topic of debate. Whether anti-depressant drug use causes suicidal thinking or behavior in adult or pediatric patients is a critically important question that we must answer in a careful, thoughtful manner.”).

the drug safety of drugs already in the marketplace.⁷⁷ The Board is comprised of medical experts from the FDA, the Department of Health and Human Services, and other federal agencies, including the Department of Veterans Affairs.⁷⁸ The Board also consults with outside medical, patient, and consumer groups. The Board works to educate key audiences about “emerging information for both previously and newly approved drugs about possible serious side effects or other safety risks that have the potential to alter the benefit-risk analysis of a drug, affect patient selection or monitoring decisions, or that can be avoided through measures taken to prevent or mitigate harm.”⁷⁹ The Board also has the authority to help resolve disagreements over drug safety issues and oversee the development of CDER’s drug safety policies.⁸⁰

III. The Development of Prescription Drug Liability

As with the FDA’s regulatory structure, the body of tort law that has developed regarding the manufacture and sale of prescription drugs recognizes that harmful side effects are bound to occur because prescription drugs are “unavoidably unsafe.”⁸¹ The law also recognizes that, because the FDA uses exacting regulations to tightly manage the public risks associated with these products, the approach for prescription drug liability differs from that of other products.⁸²

77. *Leavitt: Reforms Will Improve Oversight and Openness at FDA*, FDA CONSUMER, May-June 2005 [hereinafter *Leavitt: Reforms*] (quoting Secretary of Health and Human Services Michael Leavitt as saying “The public has spoken and they want more oversight and openness . . . They want to know what we know, what we do with the information, and why we do it. We will address their concerns by cultivating openness and enhanced independence.”), available at http://www.fda.gov/fdac/features/2005/305_drug.html.

78. U.S. Food & Drug Admin., FDA Fact Sheet: FDA Improvements in Drug Safety Monitoring (Feb. 15, 2005), available at <http://www.fda.gov/oc/factsheets/drugsafety.html>.

79. *Leavitt: Reforms*, *supra* note 77 (stating that the Board will post information on the FDA’s website, send regular updates for healthcare professionals, and boil down information for consumer comprehension).

80. *Id.*

81. See RESTATEMENT (SECOND), *supra* note 8, § 402A cmt. k.

82. See RESTATEMENT THIRD, *supra* note 8, §6 cmt. b (“The traditional refusal by courts to impose tort liability for defective designs of prescription drugs and medical devices is based on the fact that a prescription drug or medical device entails a unique set of risks and benefits. . . . This deference also rests on [the assumption that] governmental regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous designs off the market.”).

A. The Law Has Treated Prescription Drug Liability Differently from Liability Stemming from Other Products

In the 1960s, strict products liability emerged for mismanufactured products of all kinds.⁸³ Under strict liability, as formalized in section 402A of the *Restatement (Second) of Torts* in 1965, courts held product manufacturers liable for injuries caused by defective products even if “all possible care” had been exercised in making, marketing, and selling those products.⁸⁴ The law focused solely on the product, assessing whether there was a manufacturing defect, namely that a product was not made in accordance with the manufacturer’s own standards.⁸⁵ The classic example of a manufacturing defect is the case where a consumer opened a bottle of soda and found mouse droppings and a decomposed mouse that, according to the court’s findings, were in the bottle before liquid was added during the manufacturing process.⁸⁶ If such a manufacturing defect were to cause harm, the plaintiff could sue under strict liability and would not have to satisfy the requirements of traditional negligence or warranty actions. Liability would attach even if the manufacturer had acted reasonably in making the product.⁸⁷ Gradually, “strict liability” extended beyond manufacturing cases to claims brought on the basis of failure to warn or defective design.⁸⁸ Courts initially struggled with applying strict liability in these types of cases.⁸⁹

83. The first case adopting strict liability was in 1944. *See Escola v. Coca-Cola Bottling Co.*, 150 P.2d 436 (Cal. 1944). The doctrine became more widely accepted with Judge Traynor’s decision in *Greenman v. Yuba Power Prods., Inc.*, in which he wrote that a “manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.” 377 P.2d 897, 900 (Cal. 1963).

84. RESTATEMENT (SECOND), *supra* note 8, § 402A.

85. *See generally* RESTATEMENT (SECOND), *supra* note 8, § 402A.

A careful examination of the Appendix to Section 402A of the *Restatement* and discussions by the eminent Professor John W. Wade, who later became the reporter for the *Restatement* itself, show that all of the cases that were considered involved *mismanufactured* products — contaminated food products or products with construction defects. These were cases where products contained foreign objects, were missing important parts, or were not assembled in accordance with the manufacturer’s own design plans.

Schwartz, *Comment K*, *supra* note 35, at 1139 (citations omitted).

86. *Shoshone Coca-Cola Bottling Co. v. Dolinski*, 420 P.2d 855 (Nev. 1966).

87. *See* RESTATEMENT (SECOND), *supra* note 8, § 402A(2)(a) (stating that the rule applies even though “the seller has exercised all possible care in the preparation and sale of his product”).

88. *See, e.g.*, *Cronin v. J. B. E. Olson Corp.*, 501 P.2d 1153 (Cal. 1972).

89. *See generally* John W. Wade, *On Product “Design Defects” and Their Actionability*,

The *Restatement (Second)*, in comment k of section 402A, avoids confusion for design and failure to warn defects with respect to prescription drugs. Comment k states that it would be unfair to apply strict liability to design defects “in the field of drugs” because vaccines and prescription drugs are “incapable of being made safe for their intended and ordinary use.”⁹⁰ For example, as the *Restatement (Second)* observes, the Pasteur treatment of rabies can lead to serious and damaging side effects: “[s]ince the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve.”⁹¹

The *Restatement (Second)* applies this premise to all prescription drugs.⁹² It states that while these products are “[u]navoidably unsafe,” when “accompanied by proper directions and warning,” they are not “unreasonably dangerous.”⁹³ In so doing, the *Restatement (Second)* offers a fault-based liability system for design defects for prescription drugs and vaccines.⁹⁴ If a drug manufacturer meets a reasonable standard of care for both design and labeling, the product is not defective.⁹⁵ Consequently, if a person experiences a side effect caused by such a non-defective drug, that person will have a claim against the manufacturer only if the manufacturer violated some other liability theory,⁹⁶ namely negligence, fraud, or express warranty.⁹⁷

B. Judicial Reaction to Comment k

Courts have overwhelmingly agreed with the premise of comment k, that is, that the “unreasonably dangerous” test and not strict liability should be

33 VAND. L. REV. 551 (1980) [hereinafter Wade, “*Design Defects*”].

90. RESTATEMENT (SECOND), *supra* note 8, § 402A cmt. k. Dean Prosser, reporter for the *Restatement (Second)*, chose to handle prescription drug liability in a comment rather than a separate section. See *Brown v. Superior Court*, 751 P.2d 470, 475 (Cal. 1988).

91. RESTATEMENT (SECOND), *supra* note 8, § 402A cmt. k.

92. *Id.* (“It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk.”).

93. *Id.*

94. *Id.*

95. Schwartz, *Comment K*, *supra* note 35, at 1141.

96. See generally *id.*

97. Express warranty is “based on the fact that the defendant made a specific representation about a product’s safety; plaintiff relied on that representation, and it turned out to be untrue.” Victor E. Schwartz, *Violation of Express Warranty: A Useful Tort that Must Be Kept Within Rational Boundaries*, 3 PRODS. LIAB. L.J. 147, 148 (1992) [hereinafter Schwartz, *Express Warranty*].

applied to design defects for unavoidably unsafe prescription drugs.⁹⁸ By the late 1980s, however, there was a split among courts as to how the fault-based standard in comment k should be applied to prescription drugs.⁹⁹ The courts debated whether comment k should apply to all prescription drugs and whether the same rules applied for both foreseeable and unforeseeable risks.¹⁰⁰

A number of state high courts, such as the California Supreme Court in *Brown v. Superior Court*,¹⁰¹ held that all prescription drugs were unavoidably unsafe regardless of whether the risks were foreseeable, as in the case of the rabies vaccine, or unforeseeable, as was, and has been the case, with a number of modern prescription medicines.¹⁰² In *Brown*, plaintiffs brought claims against numerous drug manufacturers alleging that their product, diethylstilbestrol (DES), injured them *in utero* when their mothers took DES to prevent miscarriages.¹⁰³ The California high court concluded that “a drug manufacturer’s liability for a defectively designed drug should not be measured by the standards of strict liability,” and that “because of the public interest in the development, availability, and reasonable price of drugs, the appropriate test for determining responsibility is the test stated in comment k.”¹⁰⁴ Under the court’s comment k analysis, it held that the manufacturers “neither knew nor could have known by the application of scientific knowledge available at the time of distribution that the drug could produce the undesirable side effects suffered by the plaintiff.”¹⁰⁵ In issuing its holding, the court applied a fault-based standard to all prescription drugs regardless of the foreseeability of risks.

Several other courts, while agreeing that unavoidably unsafe products should not be treated under a theory of strict liability, held that whether a specific drug was unavoidably dangerous and, therefore, not appropriate for

98. “Comment k has been adopted in the overwhelming majority of jurisdictions that have considered the matter.” *Brown v. Superior Court*, 751 P.2d 470, 476 (Cal. 1988) (citing *DeLuryea v. Winthrop Labs.*, 697 F.2d 222, 228-29 (8th Cir. 1983); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425-26 (2d Cir. 1969); *Stone v. Smith, Kline & French Lab.*, 447 So. 2d 1301, 1303-04 (Ala. 1984); *Gaston v. Hunter*, 588 P.2d 326, 338-41 (Ariz. Ct. App. 1978); *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 380-81 (D. Md. 1975); *Johnson v. Am. Cyanamid Co.*, 718 P.2d 1318, 1323 (Kan. 1986)). “We are aware of only one decision that has applied the doctrine of strict liability to prescription drugs.” *Id.* (citing *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 654-57 (1st Cir. 1981)).

99. *Compare Brown*, 751 P.2d at 470, with *Toner v. Lederle Labs.*, 732 P.2d 297 (Idaho 1987).

100. *See, e.g., Brown*, 751 P.2d at 481-83; *Toner*, 732 P.2d at 303-09.

101. 751 P.2d 470.

102. *Id.* at 476.

103. *See id.* at 473.

104. *Id.* at 477.

105. *Id.* at 480.

strict liability, should be made on a case-by-case basis by the presiding trial judge. For instance, in *Toner v. Lederle Laboratories*¹⁰⁶ a three-month old boy was vaccinated against diphtheria, pertussis, and tetanus (DPT vaccine) and subsequently became permanently paralyzed from the waist down.¹⁰⁷ That particular vaccine was the only licensed immunization available for pertussis, despite the fact that it came with a risk of paralysis.¹⁰⁸ In deciding how to apply comment k to this case, the court said that comment k did not abolish strict liability for all prescription drugs, just those where the seller could “establish that the product’s risk is in fact ‘unavoidable.’”¹⁰⁹ The court would conduct “a full evidentiary hearing” on a case-by-case basis to recalculate the risk balancing for each drug.¹¹⁰ The defense would have to show that there was “no feasible alternative design that, on balance, accomplishes the subject product’s purpose with a lesser risk.”¹¹¹ If a defendant could not meet that test, a trial could commence to determine whether the side effect resulted from a design or warning defect, thereby triggering strict products liability for design and warning defects in some prescription drugs.¹¹²

Courts, such as the one in *Brown*, have rejected this approach, saying that under a system of mini-trials, there would be no way to predict which standard of liability would apply to a particular drug, as a court’s decision would rest on whether a particular judge — not medical science — found a drug to be defective in design, “exceptionally important,” or “highly desirable.”¹¹³ The *Brown* court also expressed concern with allowing “the question of superiority of one drug over another . . . to be decided . . . in reference to the plaintiff, since the advantages of a drug cannot be isolated from the condition of a particular plaintiff.”¹¹⁴ A federal court applying Louisiana law in *Williams v. Ciba-Geigy Corp.*¹¹⁵ reached the same conclusion: “[r]ather than simply permitting juries to apply, haphazardly and case-by-case, the risk-utility test

106. 732 P.2d 297 (Idaho 1987). For more recent cases on this point, see *Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723 (Ga. Ct. App. 2003); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827 (Neb. 2000).

107. *Toner*, 732 P.2d at 299.

108. *Id.* at 300.

109. *Id.* at 305.

110. *Id.* at 308-09.

111. *Id.* at 306.

112. *Id.* at 308-09.

113. See *Brown v. Superior Court*, 751 P.2d 470, 481, 482 (Cal. 1988) (citing *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 812 (Cal. Ct. App. 1985)). (expressing concern that because this process relies on the subjective opinion of individual jurists, judges in various parts of the country could arrive at different conclusions).

114. *Id.* at 481.

115. 686 F. Supp. 573 (W.D. La. 1988).

whenever harm results, the court must require, as a part of the plaintiff's burden of producing evidence, an articulable basis for disregarding the FDA's determination that the drug should be available."¹¹⁶

IV. The Current Liability Regime for Prescription Drugs

In an effort to provide greater clarity to this debate and emphasize the unique nature of prescription drug liability, the new *Restatement of Torts, Third: Products Liability*, adopted in 1997, offered a distinct section solely on the liability framework associated with product defects in prescription drugs and medical devices.¹¹⁷ Private plaintiff and defense lawyers collaborated with academics and judges to produce the *Restatement Third*.¹¹⁸ Section 6 focuses solely on medical liability and sets forth when there can be a claim for a manufacturing, design, or failure to warn defect.¹¹⁹

A. Manufacturing Defect

The *Restatement Third* states that "a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device . . . contains a manufacturing defect as defined in § 2(a)," the section of the *Restatement Third* that defines manufacturing defect law for other products.¹²⁰ Consequently, a drug has a manufacturing defect "when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product."¹²¹ Because the product is not in its "intended condition," it is "defective in the normal sense of the expression. . . . [A]ll that the plaintiff must do is show that the product was in the dangerous condition when it left the defendant's control."¹²² The manufacturer faces strict liability for injuries caused by the manufacturing defect, even in the absence of negligence.¹²³

116. *Id.* at 577 (applying Louisiana law).

117. See RESTATEMENT THIRD, *supra* note 8, § 6; Mark A. Dotson, *Restatement Third and Prescription Drug Liability: A Tough Pill to Swallow or Business as Usual?*, 4 T.M. COOLEY J. PRAC. & CLINICAL L. 29, 29 (2000); see also *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741 (W.D. Pa. 2004) (applying these principles to medical devices under Pennsylvania law).

118. See Geoffrey C. Hazard, Jr., *Foreword* to RESTATEMENT OF TORTS, THIRD: PRODUCTS LIABILITY, at xv, xvi (1998) (observing that the Restatement states where the law currently stands and how it is changing).

119. See RESTATEMENT THIRD, *supra* note 8, § 6.

120. *Restatement Third* section 6(b)(1) refers back to section 2(a), which defines manufacturing defect law for general product defects. RESTATEMENT THIRD, *supra* note 8, § 6.

121. RESTATEMENT THIRD, *supra* note 8, § 2.

122. Wade, "Design Defects," *supra* note 89, at 551, 553.

123. See *id.* at 552 ("[I]t is not in regard to this element that a distinction is to be drawn

No controversy exists over manufacturing defect law for prescription drugs.¹²⁴ As with other products, strict liability in the manufacturing of prescription drugs creates appropriate incentives for companies to ensure good quality control and that their products are made as intended.¹²⁵ Thus, the *Restatement Third* was faithful to the original purpose and scope of strict products liability, namely applying it only to manufacturing defects.¹²⁶

B. Design Defect

With regard to design defect, the *Restatement Third* states that

[a] prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable [healthcare] providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.¹²⁷

1. Strict Liability Is Not Appropriate for All Prescription Drugs

As the *Restatement Third* observes, design defect liability for all prescription drugs fundamentally differs from other products.¹²⁸ Under traditional products liability law, as set forth in section 2(b) of the *Restatement Third*, a product manufacturer faces liability for a design defect when the “foreseeable risks of harm” could have been “reduced or avoided” through a “reasonable alternative design.”¹²⁹ Any such risk-utility balancing of a

between negligence and strict liability.”).

124. “This limitation on the scope of comment k immunity is universally recognized.” *Grundberg v. Upjohn Co.*, 813 P.2d 89, 92 (Utah 1991).

125. See John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 *MISS. L.J.* 825, 826 (1973) [hereinafter Wade, *Strict Tort Liability*] (listing one of the prime reasons given for embracing the strict liability approach as the deterrent effect: “Experience seems to demonstrate that if a manufacturer knows he will be held liable for injuries inflicted by his product, that product will be safer than if he understands that he can avoid liability by demonstrating the exercise of due care.”).

126. See *RESTATEMENT THIRD*, *supra* note 8, § 2 cmt. a.

127. See *id.* § 6(c).

128. *Id.* § 6.

129. *Id.* § 2. The *Restatement Third* does not view the expectations of the consumer as an independent standard for judging the defectiveness of product designs, except with respect to food and used products. “Consumer expectations, standing alone, do not take into account whether the proposed alternative design could be implemented at reasonable cost, or whether an alternative design would provide greater overall safety.” *Id.* § 2 cmt. g, at 27. In addition, the consumer is defined differently in the prescription drug market, as the medical and legal

product's design by courts presumes that there are other ways to make a product and compares the design in question to state-of-the-art knowledge and industry practice.¹³⁰

This comparison cannot be made for prescription drugs, as each drug is a unique formulation that must be specifically approved by the FDA.¹³¹ For example, COX-2 inhibitors, such as VIOXX and Celebrex, are each unique products, not alternative designs of each other. The standard also cannot be assessed by the impact that a drug has on any particular individual. Because the chemical compounds in prescription drugs "interact with the chemical and physiological processes of the human body, they will almost always pose some risk of side effects in certain individuals."¹³² So while a particular formulation may be the saving grace for one patient, it may be harmful to another.¹³³ For these reasons, the "reasonable alternative design" standard should not define whether a prescription drug has a design defect.¹³⁴

2. Courts Should Apply "Reasonable" Medical and Research Standards for the Design of Prescription Drugs

The *Restatement Third* replaces the reasonable alternative design standard with a "reasonable health-care provider" standard.¹³⁵ Under this standard, a drug only has a design defect when no reasonable health provider, knowledgeable in the risks and benefits of the drug, would prescribe the drug to any patient.¹³⁶ In these situations, the drug offers no net benefit to any class of patients and the manufacturer faces strict liability for adverse reactions caused by its drug.¹³⁷ According to the *Restatement Third*, this standard is

community uniformly considers the doctor, not the patient, to be the consumer of prescription drugs. See *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988).

130. See RESTATEMENT THIRD, *supra* note 8, § 2 cmt. d.

131. See *generally* 21 C.F.R. pt. 314 (2005).

132. *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991).

133. RESTATEMENT THIRD, *supra* note 8, § 6 cmt. b.

134. See *Brown*, 751 P.2d at 478 ("[T]here is no possibility for an alternative design for a drug like DES, which is a scientific constant compounded in accordance with a required formula.").

135. RESTATEMENT THIRD, *supra* note 8, § 6 cmt. f.

136. See *id.* § 6(c).

137. This concept tracks with traditional products liability law, which allows a court to determine that a product, with no reasonable alternative design is defective because it simply is not reasonably safe. The *Restatement Third* defines such products as those where "the extremely high degree of danger posed by its use or consumption so substantially outweighs its negligible social utility that no rational, reasonable person, fully aware of the relevant facts, would choose to use, or to allow children to use, the product." *Id.* § 2 cmt. e, at 22.

objective and “very demanding” to satisfy: “liability is likely to be imposed only under unusual circumstances.”¹³⁸

To meet its obligation under the “reasonable health-care provider” standard, the *Restatement Third* states that a drug manufacturer must undertake “reasonable research” to determine the risks and benefits of a drug before taking it to market.¹³⁹ This standard inherently recognizes that it is not possible to uncover every potential side effect that a particular drug may cause. The FDA uses its formal rule-making process to review this research and determine if more research is needed in order for an application to be complete.¹⁴⁰ When the drug’s chemical make-up provides inherent risks of side effects that are unavoidable for some patients, the FDA requires the drug to be available only through a doctor’s prescription.¹⁴¹ Thus, for the FDA’s approval process to have any meaning, the requirements of the FDA’s NDA program must set the legal standard for what constitutes “reasonable” research for each prescription drug.¹⁴²

Allowing courts to second-guess FDA assessments in hindsight, as the *Toner* court would have them do,¹⁴³ ignores the unique nature of the FDA regulatory process. Other federal agencies, such as National Highway Transportation Safety Agency or the Consumer Protection Safety Commission, have been found by some courts to set “minimum” safety standards for products.¹⁴⁴ Manufacturers of products subject to these controls may be due a rebuttable presumption when sued for conduct compliant with those standards.¹⁴⁵ The FDA, on the other hand, must specifically approve for

138. *Id.* § 6 cmt. f, at 149. Because this is an objective standard, a court must determine what a “reasonable” physician would do and cannot be swayed by the passionate testimony of any one doctor that he or she would or would not prescribe the drug. *Id.*

139. *See id.* § 6 cmt. g, at 150 (“Drug and medical device manufacturers have the responsibility to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal.”).

140. 21 C.F.R. § 314.105(c) (2005).

141. *See* 21 U.S.C. § 353(b)(1)(A) (2000) (stating that a drug requires a prescription “because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug”).

142. *See* RESTATEMENT THIRD, *supra* note 8, § 6 cmt. g (“Courts have also recognized that the regulatory system governing prescription drugs is a legitimate mechanism for setting the standards for drug design.”); *see also* Grundberg v. Upjohn Co., 813 P.2d 89, 89 (Utah 1991) (finding that the FDA is “capable of and appropriate for making the preliminary determination regarding whether a prescription drug’s benefits outweigh its risks”).

143. *See* *Toner v. Lederle Labs.*, 732 P.2d 297, 307 (Idaho 1987).

144. RESTATEMENT (SECOND), *supra* note 8, § 288C cmt. a; *see* Grand Trunk Ry. Co. v. Ives, 144 U.S. 408 (1892) (pioneering the concept of minimum standards).

145. *See* discussion *infra* Part VI.B.

market each prescription drug and agree to all instructions and warnings with regards to risks and side effects.¹⁴⁶ Because of these tight controls, courts have allowed regulatory agencies to determine that a specifically approved product is not legally defective.¹⁴⁷ With the FDA defining the standard of care that drug manufacturers owe consumers, a manufacturer has a significant incentive — the opportunity to protect itself from a design defect claim — to meet every requirement and turn over all pertinent information, including all adverse risk reports and background studies, to the FDA.¹⁴⁸

For this and the other foregoing reasons, several courts, including the Supreme Courts of Utah and Washington, both of which have been particularly sensitive to the rights of plaintiffs,¹⁴⁹ have applied the unavoidably dangerous products doctrine to all prescription drugs for both foreseeable and unforeseeable risks.¹⁵⁰ As the Supreme Court of Utah concluded, “all

146. See discussion *supra* Part II.B.

147. In a traditional regulatory compliance defense analysis, the key question is whether the regulatory scheme establishes minimum standards or “an optimal cost-benefit balance struck by the agency.” 2 REPORTERS’ STUDY, *supra* note 1, at 108; see also *Grundberg*, 813 P.2d at 89 (“The federal government has established an elaborate regulatory system, overseen by the FDA, to control the approval and distribution of these drugs. No other class of products is subject to such special restrictions or protections in our society.”) (citation omitted).

148. “Under regulation innovators are likely to face a long, costly, and uncertain process of screening and clearance before being allowed to deploy new products or processes. . . . In return for paying the up-front ‘price’ of enduring the regulatory gauntlet, the enterprise obtains reasonable investment security.” 2 REPORTERS’ STUDY, *supra* note 1, at 88. Where regulations do not govern pre-market activity, “the price for this freedom is continuing exposure to future liabilities.” *Id.*

149. For plaintiff rights decisions by the Supreme Court of Utah, consider the following cases: *Campbell v. State Farm Mutual Automobile Insurance Co.*, 98 P.3d 409 (Utah 2004) (defying the language and the spirit of the decision by the Supreme Court of the United States on punitive damages in *State Farm Mutual Automobile Insurance Company v. Campbell*); *Sun Valley Water Beds of Utah, Inc. v. Herm Hughes & Son, Inc.*, 782 P.2d 188 (Utah 1989) (holding that the architects and builders statute of repose violated the open courts provision of the state constitution); *Berry v. Beech Aircraft Corp.*, 717 P.2d 670 (Utah 1985) (holding that the statute of repose barring product liability claims six years after the purchase or ten years after the date of manufacture of a product violated the access to courts provision of the state constitution). For plaintiff rights decisions by the Supreme Court of Washington, consider the following cases: *DeYoung v. Providence Medical Center*, 960 P.2d 919 (Wash. 1998) (holding that the state’s eight-year statute of repose for medical malpractice actions violated the privileges and immunities clause of the state constitution); *Sofie v. Fibreboard Corp.*, 771 P.2d 711 (Wash. 1989) (holding that the variable limit on noneconomic damages awards violated the right to trial by jury under the state constitution); *Kirk v. Washington State University*, 746 P.2d 285 (Wash. 1987) (permitting recovery for hedonic loss as a separate element of damages by drawing technical distinctions between the concepts of pain and suffering, disability, and lost enjoyment of life).

150. See *Young v. Key Pharm., Inc.*, 922 P.2d 59 (Wash. 1996); *Grundberg*, 813 P.2d at 89.

prescription drugs should be classified as unavoidably dangerous in design because of their unique nature and value, the elaborate regulatory system overseen by the FDA, the difficulties of relying on individual lawsuits as a forum in which to review a prescription drug's design, and [for] significant public policy considerations.”¹⁵¹

The Supreme Court of Washington agreed: “a separate determination of whether a product is unavoidably unsafe need not be made on a case-by-case basis if that product is a prescription drug.”¹⁵² Other courts, appreciating the sound public policy balancing of the Utah and Washington courts, have ruled similarly.¹⁵³

C. Defects Due to Failure to Warn

The *Restatement Third* defines failure to warn defect as follows:

A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other [healthcare] providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

151. *Grundberg*, 813 P.2d at 95. A drug that is “properly prepared, compounded, packaged, and distributed, cannot as a matter of law be ‘defective’ in the absence of proof of inaccurate, incomplete, misleading, or fraudulent information furnished by the manufacturer in connection with FDA approval.” *Id.* at 90.

152. *Young*, 922 P.2d at 64.

153. *See, e.g.*, *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) (in a case involving the prescription drug Celebrex, the federal district court, applying Texas law, held that all prescription drugs are unavoidably dangerous and that a prescription drug manufacturer can only be held strictly liable “if the drug was not properly prepared or marketed or accompanied by proper warnings”); *Doe v. Solvay Pharm., Inc.*, 350 F. Supp. 2d 257, 267 (D. Me. 2004) (interpreting Maine law); *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996) (“[r]eaffirming that the basis of liability in [a prescription drug] case is the failure to exercise reasonable care rather than strict liability . . . [in reliance] on the principles set forth in comments j and k”); *Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1337 (9th Cir. 1985) (holding that the oral polio vaccine was unavoidably unsafe under comment k); *Fellows v. USV Pharm. Corp.*, 502 F. Supp. 297, 300 (D. Md. 1980) (suggesting that Maryland would likely follow the approach of courts that have held that prescription drugs are not unreasonably dangerous and manufacturers would only be liable if they failed to provide adequate warnings); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90-91 (2d Cir. 1980) (finding that “unavoidably unsafe” prescription drugs are not defective or unreasonably dangerous if accompanied by directions and warnings).

(2) the patient when the manufacturer knows or has reason to know the [healthcare] providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.¹⁵⁴

Thus, the *Restatement Third* applies a “reasonable” test, not strict liability, to failure to warn defect law; the obligation of the manufacturer is to provide adequate and reasonable warnings to the prescribing physician or other similarly situated health provider so that they can prescribe the drug safely and effectively.¹⁵⁵ If such warnings are not adequate or not provided to the physician, a manufacturer may be subject to liability for any injury caused by the breach.¹⁵⁶

1. Defining Adequate Warning

The *Restatement Third* defines adequate warning as “reasonable instructions or warnings regarding foreseeable risks of harm.”¹⁵⁷ This “reasonable” standard allows the substance of the warnings to correspond with the potential deficiencies discovered during the pre-market research into the drug’s design. Thus, as with design defect, the only way to implement this liability structure is for the FDA to determine which warnings are “reasonable” and “foreseeable” for each prescription drug.¹⁵⁸

154. RESTATEMENT THIRD, *supra* note 8, § 6(d).

155. See RESTATEMENT THIRD, *supra* note 8, § 6; see also *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 838 (Ohio 1981) (stating that, under comment j of the *Restatement (Second)*, there is “a presumption that an adequate warning, if given, will be read and heeded”).

156. In situations where doctors prescribe drugs for purposes that ignore warnings and go beyond risks approved by the FDA, the doctors are responsible for harms that stem from new and unapproved uses. *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 887-88 (Minn. 1970). Since *Mulder*, a majority of courts have allowed into evidence the information included in the packaging. Though not conclusive, such evidence aids in determining whether a physician violated his standard of care to a patient. Some courts have held that manufacturer-provided information sets the standard of care for the physicians; other courts allow manufacturer-provided information to be evidence of notice of certain potential side effects or the basis for an expert opinion. Glenn E. Bradford & Charles C. Elben, *The Drug Package Insert and the PDR as Establishing the Standard of Care in Prescription Drug Liability Cases*, 57 J. MO. B. 233, 234, 238 (2001) (discussing case law relevant to suits against physicians for off-label use). A manufacturer of prescription drugs would only be subject to liability for “off label” use of its prescription drug if the company actively encouraged that “off label” use, as a manufacturer must submit a supplemental new drug application and receive FDA approval to promote a new use for an existing drug and to include that new use on the packaging. 59 Fed. Reg. 59,820 (Nov. 18, 1994). If the label includes information about an unapproved use, the label would be “misbranded,” subjecting the manufacturer to FDA enforcement actions. See *Wash. Legal Found. v. Henny*, 202 F.3d 331, 332-33 (D.C. Cir. 2000) (citing 21 U.S.C. §§ 331(a), 352(a)).

157. RESTATEMENT THIRD, *supra* note 8, § 6.

158. See Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food*

Courts are generally in agreement that this standard *must* be applied at the time of marketing, not afterwards. For example, the Supreme Court of Washington heard a case in which the plaintiff alleged that the defendant failed to warn doctors about possible complications of a time-release asthma medication for a three-year-old boy.¹⁵⁹ A viral infection and fever elevated the presence of the drug in his system, causing a seizure.¹⁶⁰ The jury ruled for the defense.¹⁶¹ On appeal, the court found that “the state of knowledge about the relationship between fevers or viral illnesses and [the drug] was not yet clinically reliable and that it would have been irresponsible for the drug company to warn of risks that were not yet proven to be legitimate risks.”¹⁶² The court further recognized that “[e]ven where a drug . . . has been in use for a number of decades, it is obviously impossible to know absolutely that every risk attendant to its use is already known. . . . [I]t is precisely because they are unavoidably unsafe to some degree that they are prescription drugs.”¹⁶³ Even the court in *Toner* agreed with this premise, stating, “[t]he weighing must be done as of the time the product is distributed to the plaintiff. Comment k does not require sellers to be clairvoyant.”¹⁶⁴

Therefore, a drug manufacturer can only warn of harms it knew or should have known as a result of reasonable research at the time of marketing.¹⁶⁵ Should after-market results indicate a need to modify warnings or instructions, the company must seek approval from the FDA for the changes. The new wording must accurately reflect the best scientific evidence,¹⁶⁶ not fear or concern about a potential reaction, or a desire to avoid potential litigation.

and Drug Administration, 41 FOOD DRUG COSM. L.J. 233, 236 (1986) (stating that the FDA “retains, as a practical matter, complete control over package inserts”); *see also* Richard Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 100 (2002) [hereinafter Ausness, *Aggressive Marketing Practices*] (the FDA has authority over any information that could reach a doctor or patient, including brochures, letters, and advertising).

159. *Young v. Key Pharm., Inc.*, 922 P.2d 59, 61-62 (Wash. 1996).

160. *Id.* at 64.

161. *Id.* at 62.

162. *Id.*

163. *Id.* at 64, 65 n.4.

164. *Toner v. Lederle Labs.*, 732 P.2d 297, 306-07 (Idaho 1987) (citations omitted).

165. *See Brown v. Superior Court*, 751 P.2d 470, 486 n.4 (Cal. 1988). In a failure to warn case, to prove proximate causation, the plaintiff also would have to show that a different warning would have prevented the alleged injury. *See, e.g., Dyson v. Winfield*, 113 F. Supp. 2d 35, 41 (D.D.C. 2000) (whether or not the warning is defective, plaintiff still must show that the doctor would have changed the prescription).

166. *Cf.* 21 C.F.R. § 1.21 (2005) (stating the requirement for all material information to be included on a label).

2. *The Learned Intermediary Doctrine*

The law treats the prescribing physician as the person legally responsible for reading warnings and evaluating a patient's medical condition to determine if a particular drug would benefit a particular patient, given the drug's inherent risks.¹⁶⁷ The physician is called the "learned intermediary."¹⁶⁸

Under this "learned intermediary" doctrine, the doctor, not the patient, takes the role of primary decision-maker in determining whether a patient should take a drug, and if so, which drug.¹⁶⁹ Consequently, prescription drug warnings and instructions are not meant for the consumer, but the physician, who bears the responsibility of ensuring that the medication is not over-prescribed and monitoring the patient's reaction to the drug.¹⁷⁰ The manufacturer bears the responsibility of providing warnings, instructions, and other relevant guidance information to the prescribing physician,¹⁷¹ which it does through the *Physicians' Desk Reference* (PDR), a reference guide containing "exact" copies of the FDA approved labels of prescription drugs.¹⁷² The manufacturer also can convey these instructions and guidance materials

167. See, e.g., *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1031-32 (D.N.J. 1988) ("Once the physician has been warned, it is the physician's duty to decide which drug to use and to explain the risks involved. Because prescription drugs are often complex in formula and effect, the physician is in the best position to take into account the propensities of the drug and the susceptibilities of the patient, and to give a highly individualized warning to the ultimate user based on the physician's specialized knowledge.") (citations omitted).

168. *Id.* at 1032.

169. See *Ausness, Aggressive Marketing Practices*, *supra* note 158, at 108; see also *Doe v. Solvay Pharm., Inc.*, 350 F. Supp. 2d 257, 272 (D. Me. 2004) (stating that under Maine law, there is "a presumption that if an adequate warning is given [to] the physician, it will be read and heeded" by the physician).

170. See *Bradford & Elben*, *supra* note 156, at 233 ("The insert is directed to the physician and is not customarily seen by the patient.").

171. *Brown v. Superior Court*, 751 P.2d 470, 477-78 (Cal. 1988) ("The manufacturer cannot be held liable if it has provided appropriate warnings and the doctor fails in his duty to transmit these warnings to the patient or if the patient relies on inaccurate information from others regarding side effects of the drug."). With the advent of the Internet, the spread of inaccurate information collected at various websites can lead to significant misinformation. Drug manufacturers also have a continuing duty to warn the medical community of "risks or side effects that are discovered after the product is first marketed." *Ausness, Aggressive Marketing Practices*, *supra* note 158, at 107-08.

172. See *Foreword to the Fifty-Ninth Edition of PHYSICIANS' DESK REFERENCE* (59th ed. 2005). In accordance with federal regulations, the *Physicians' Desk Reference* includes "indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant warnings, hazards, contraindications, side effects, and precautions" for each drug. *Id.* (quoting 21 C.F.R. § 201.100(d)(1) (2005)).

directly to prescribing physicians and pharmacists, such as through direct mail and package inserts.¹⁷³

This structure is based on the fact that patients generally do not have the training or are not properly situated to undertake the complex endeavor of assessing medical risk-benefit analyses.¹⁷⁴ First, given the anxiety that may accompany the medical condition necessitating the prescription drug, patients and their families are not likely to be in the proper mind set to make such calculations. Second, warnings are written in technical terms with broad application. It would be impractical for a drug company to distill the risk analysis into lay language or to tailor the risk analysis to individual patients and their unique medical conditions and histories.¹⁷⁵ Third, imposing a duty to warn patients directly “would interfere with the relationship between the doctor and the patient.”¹⁷⁶

In one recent case before the Supreme Court of Connecticut, *Vitanza v. Upjohn Co.*,¹⁷⁷ the court applied the learned intermediary doctrine to bar a claim from a woman whose husband developed a fatal allergic reaction to her nonsteroidal anti-inflammatory drug (NSAID).¹⁷⁸ The manufacturer knew its product could cause fatal reactions in those allergic to aspirin or other NSAIDs and included such a warning in its package insert and PDR listing, but not on its sample packets.¹⁷⁹ The husband, aware that he was allergic to NSAIDs and not seeing a warning on the sample packet his wife received from her doctor, took the NSAID; he died shortly thereafter from severe respiratory and cardiac arrest.¹⁸⁰ The court held that the manufacturer fulfilled its duty to inform the physician.¹⁸¹ It also listed more than forty states or jurisdictions that have

173. See Bradford & Elben, *supra* note 156, at 234. Pharmacists generally receive inserts as part of bulk shipments. They break down the bulk shipment to fill individual prescriptions. Therefore, the information is not conveyed directly from the manufacturer to the patient at either prescription or at delivery. See Ausness, *Aggressive Marketing Practices*, *supra* note 158, at 109-10.

174. Ausness, *Aggressive Marketing Practices*, *supra* note 158, at 109.

175. See *West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991) (finding that “it is virtually impossible in many cases for a manufacturer to directly warn each patient”).

176. *Id.*

177. 778 A.2d 829 (Conn. 2001).

178. *Id.* at 832.

179. *Id.* at 833 (The package insert stated “ANSAID should not be given to patients in whom ANSAID, aspirin or other [NSAIDs] induce asthma, urticaria, or other allergic-type reactions. Fatal asthmatic reactions have been reported in such patients receiving this type of drug.”). *Id.* at 833-34.

180. *Id.* at 834.

181. *Id.* at 847.

adopted the learned intermediary doctrine, saying that the “wealth of decisions adopting the doctrine is highly persuasive.”¹⁸²

Courts have found only a few instances where warnings need to be communicated directly to the patient in order for the manufacturer to avoid liability under failure to warn. Thus far, in all of these situations the traditional physician-patient relationships have broken down: vaccines administered by clinics to the mass public,¹⁸³ oral contraceptives,¹⁸⁴ and, in one instance, intra-uterine devices (IUDs).¹⁸⁵ It should be noted that a majority of courts have allowed the learned intermediary doctrine to apply to mass vaccinations and IUDs when manufacturers fulfill their duty by warning the purchaser, such as the Center for Disease Control, who the manufacturer either obligated or reasonably relied on to warn the consumer.¹⁸⁶

Importantly, the learned intermediary doctrine does not preclude the drug manufacturer from educating consumers directly about its prescription drugs, such as through direct-to-consumer advertising.¹⁸⁷ These communications with patients must include statements of risk consistent with the FDA approved warnings and make clear that the potential consumer’s physician, not the consumer, decides whether the patient will use the drug.¹⁸⁸

182. *Id.* at 838.

183. *See* *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968) (holding polio vaccine manufacturer liable for failure to warn consumer of risks).

184. *See* Ausness, *Aggressive Marketing Practices*, *supra* note 158, at 111.

185. *Hill v. Searle Labs., Inc.*, 884 F.2d 1064, 1071 (8th Cir. 1989). IUD cases are “atypical from most prescription drug products because the treating physician generally does not make an intervening, individualized medical judgment in the birth control decision.” *Id.* at 1070.

186. *See* *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 766 (Ky. 2004); Ausness, *Aggressive Marketing Practices*, *supra* note 158, at 112.

187. *See, e.g., Lennon ex rel. Lennon v. Wyeth-Ayerst Labs., Inc.*, No. 1793 EDA 2000, 2001 WL 755944, at *2 (Pa. Super. Ct. June 14, 2001) (holding that direct-to-consumer advertising does not overcome the basic premise that the decision for a patient to take a drug lies with the physician); *Heindel v. Pfizer, Inc.*, No. Civ.A. 02-3348(SRC), 2004 WL 1398024, at *17 (D.N.J. June 7, 2004) (applying Pennsylvania law and stating that the learned intermediary “breaks the chain in terms of reliance, since the patient cannot obtain prescription drugs without the physician no matter what they believe about them”).

188. Direct-to-consumer advertising by drug companies began in the 1980s, some ten years before the *Restatement Third* was written and published. *See* Ausness, *Aggressive Marketing Practices*, *supra* note 158, at 98. Advertisements that suggest a drug is suitable for a particular condition must include a summary of the warning information. They also tend to recommend talking with a doctor, whose prescription is required in order to take the medication. Therefore, it is unquestionably the responsibility of the prescribing doctor, and not the sponsor of the advertisement — as dictated by the learned intermediary rule — to ensure that the patients are prescribed appropriate medication. *See id.* at 99 (concluding that “subjecting pharmaceutical companies to greater tort liability will not necessarily benefit the consuming public”). *But see* *Perez v. Wyeth Labs.*, 734 A.2d 1245, 1257 (N.J. 1999) (holding, in case involving

V. The Public Policy Rationale for Complementary Regulatory and Liability Regimes

The liability system for prescription drugs recognized by the Restatements and detailed in the previous Part places incentives in the right direction: drug companies should meet the requirements of the FDA or face the threat of strict liability. A drug manufacturer acting outside of FDA authority or securing FDA approval dishonorably, such as by not providing material information in obtaining or maintaining FDA approval, should be subject to liability for design and failure to warn defects.

Conversely, if a drug manufacturer complies with FDA's exacting regulations, thereby acting reasonably in researching and marketing a drug, the drug manufacturer should not be responsible in tort law under strict liability if someone experiences a side effect. While there may be an injury, there would be no breach of an objective standard of care. In these instances, the manufacturer only should be liable for injuries caused by an objective wrongful act, such as specific acts of negligence, fraud, or breach of express warranty conducted in connection with manufacturing, marketing, or selling the prescription drug. These specific acts would go beyond conduct in accord with the normal FDA drug approval process.

In its basic form, this system assigns responsibility to pharmaceutical companies and the FDA to make macro-level health care decisions about the availability and use of prescription drugs, knowing that some people will experience certain side effects. Manufacturers would produce and market prescription drugs that benefit some class of patients. The FDA would oversee this process in accordance with the procedures discussed earlier in the article, assuring that drugs are developed under a reasonable standard of care and that warnings are given of reasonably known side effects. Such a system would allow the FDA, through regulation and enforcement, to set an appropriate national public risk strategy for each individual prescription drug. The FDA has welcomed this responsibility.¹⁸⁹

Doctors bear the responsibility, then, to weigh the risks and benefits in making the decision of whether a particular patient *should* take a particular drug.¹⁹⁰ Although a patient's need for a particular medication may be certain,

advertisements for contraception, that the learned intermediary doctrine did not apply to the direct marketing of drugs to consumers).

189. See Amicus Brief of Food and Drug Administration for the United States in Support of the Defendant-Appellee and Cross-Appellant at 16, *Motus v. Pfizer Inc.* 358 F.3d 659 (9th Cir. 2000) (Nos. 02-55372, 02-55498), available at 2002 WL 32303084 [hereinafter FDA Brief].

190. Pharmacists and physicians remain in control of patients' drug choices:

the drug may cause serious side effects, a situation that presents a choice for the doctor and patient, or patient representative. Neither the drug company nor the FDA can make that decision; only the doctors and patients can determine whether a particular drug is worth taking given the current ailment or situation of the patient. In fact, this very rationale supports the almost universally accepted learned intermediary rule.

A. The Health Care Impact of Litigation for Approved Drugs and Warnings

Before issuing the new section for medical liability in the *Restatement Third*, the *Reporters' Study* examined the impact on America's health care of subjecting prescription drug manufacturers to strict liability under design and warning defect law for designs and warnings that had been approved through the extensive FDA regulatory process.¹⁹¹ The *Reporters' Study* concluded that such a dual system would threaten American health care with paying the price of both systems without the benefit of either:

[I]f liability is retained for such risks, larger errors are likely to occur in resolving through case by case litigation issues related to the magnitude of the risk, product defects and warnings, and causation. . . . Consequently, retention of tort liability threatens to perpetuate some of the very problems that led to the creation of regulatory programs to deal with such risks.¹⁹²

As this passage indicates, regulation supplanted liability in managing the safety and effectiveness of prescription drugs, because characteristics inherent to the litigation process prevent it from competently managing public risk. For example, regulators use an open rule-making process to hear from all parties and experts to make the best decision for the country.¹⁹³ Courts use the rules of evidence and only hear from parties and their partisan experts representing narrow legal positions.¹⁹⁴ Thus, where court decisions have the effect of

The entire system of drug distribution in America is set up so as to place the responsibility of distribution and use upon professional people. The laws and regulations prevent prescription type drugs from being purchased by individuals without the advice, guidance and consent of licensed physicians and pharmacists. These professionals are in the best position to evaluate the warnings put out by the drug industry.

Gravis v. Parke-Davis & Co., 502 S.W.2d 863, 870 (Tex. Civ. App. 1973).

191. 2 REPORTERS' STUDY, *supra* note 1, at 89.

192. *Id.* at 87.

193. See Administrative Procedure Act, 5 U.S.C. § 553(c) (2000).

194. See, e.g., W. Kip Viscusi, *Toward a Diminished Role for Tort Liability*, 6 YALE J. ON REG. 65 (1989) [hereinafter Viscusi, *Toward a Diminished Role*] (discussing how market forces, regulation, litigation, and social insurance interact).

regulation, such as where a manufacturer is held liable for FDA compliant behavior, the courts' decision-making process is inadequate.

Also, prescription drug litigation requires judges and jurors to consider complicated legal, moral, and scientific topics in an emotionally charged courtroom without the time or training to wrestle with the issues.¹⁹⁵ Some individuals in the legal decision-making process, therefore, may have an understandably difficult time viewing design and warning decisions as scientific calculations based on a careful balancing of risks and benefits.¹⁹⁶

The consequences of bad courtroom decision-making, such as cases involving Bendectin™, breast implants, and certain vaccines, are well-documented.¹⁹⁷ These drugs and devices were not the "cause" of the harms alleged, yet the introduction of unsound scientific evidence on the issue of causation subjected their manufacturers to significantly disproportionate liability.¹⁹⁸ In these instances, the drug manufacturers, as a practical matter, had no choice but to pull their products off the market. Other manufacturers facing similar circumstances in the future may have to significantly increase the price of their drugs in order to offset liability and liability-related costs.¹⁹⁹

195. "Judges and juries lack the specialized experience necessary for resolving the intertwined, technical issues associated with assessing the risks and benefits of many industrial products and processes." Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual Track System*, 88 GEO. L.J. 2167, 2169 (2000); see also Rein, *supra* note 34, at 3.

196. See *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 764 (Ky. 2004) (stating that "the lay consumer might overreact to such warnings and forego beneficial, or even vital, medical treatment").

197. See, e.g., Stewart, *supra* note 195, at 2176 (stating that the tort system has a "record of error in resolving scientifically and technically complex issues and . . . inherent limitations in making appropriate risk-benefit tradeoffs").

198. See *id.* at 2171.

199. This potential decrease has been described negatively:

The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.

WILLIAM L. PROSSER, *HANDBOOK OF THE LAW OF TORTS* § 99, at 661 (4th ed. 1971). Experts generally accept that liability impacts the availability of products. For example, in responding to the terrorist attacks on September 11, 2001, Congress enacted various liability protections for manufacturers of products qualified as anti-terrorism technologies. In provisions of the Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (2002), which were labeled the "SAFETY Act," Congress barred punitive damages and prejudgment interest against the makers of such technology, established a rebuttable presumption that the manufacturer is entitled to the government contract defense, and eliminated joint and several liability for non-

Where liability-related add-ons tip the cost-benefit balance of producing a drug, they stifle the research, development, and manufacture of important, ethical drugs.²⁰⁰

Similarly, if warnings were governed by liability concerns, rational drug manufacturers would warn for every potential adverse reaction to avoid strict liability.²⁰¹ There are two problems with this approach. First, any warning that is inconsistent with language approved by the FDA would qualify the drug as misbranded and subject the manufacturer to enforcement actions.²⁰² Second, according to health advocates, the inclusion of unsubstantiated risks on a label could deter doctors and patients from making use of a drug, even if the patient would benefit from the drug and belongs to the class of patients for whom the risk-benefit trade-off is optimal.²⁰³ Such reports already have materialized in response to negative media attention and trial lawyer advertising for some drugs.²⁰⁴ The consequences can be severe; for example, when a severe mental disorder necessitates medication, not taking medication could put at risk the individual, that person's family members, and the larger community.²⁰⁵

economic damages, and other things. *See generally* 68 Fed. Reg. 59,684 (Oct. 16, 2003) (explaining the rationale for these liability protections).

200. *See* *Brown v. Superior Court*, 751 P.2d 470, 479-80 (Cal. 1988) (expressing concern that any form of strict liability could force drug manufacturers to stop producing valuable, ethical drugs — or at least delay their release — because of disproportionate liability costs or inability to obtain reasonable insurance); Schwartz, *Comment K, supra* note 35, at 1141 (“The basic message here is that, in general, ethical drugs and harms that arise out of their use should not subject their manufacturer, distributor or retailer to strict liability.”); Viscusi, *Deterring Inefficient Litigation, supra* note 52, at 1445, 1454 (It would be difficult to quantify the impact that excessive liability could have on America's health care because “the costs of drug unavailability are often in the realm of the abstract.”).

201. *See, e.g., Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1153 (Cal. 1984) (under such a system, “a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning”); W. Kip Viscusi, *Individual Rationality, Hazard Warnings, and the Foundations of Tort Law*, 48 RUTGERS L. REV. 625, 628 (1996) [hereinafter Viscusi, *Individual Rationality*] (“Tort law currently is asymmetric in terms of its structure. Firms may potentially incur tort liability penalties for underwarning. . . . The uncertainty of whether warnings meet the liability test consequently provides incentive for firms to overwarn, thus potentially diluting the efficacy of warning in other contexts as well.”).

202. *See* FDA Brief, *supra* note 189, at 6.

203. *See id.* at 23-24.

204. *See* Beth Musgrave, *Tort Advertisements Worry Some Health Advocates*, SUN HERALD (Biloxi, Miss.), Mar. 21, 2004, at A1 (reporting that “[m]ental health advocates want Mississippi television stations to quit airing an advertisement that has prompted some mentally ill patients to stop taking their medications”).

205. *See* Julia Robb, *Mental Illness Robbed Local Woman of Her True Self*, MARSHALL (TX)

Further, if hundreds of courtrooms around the country made risk-benefit decisions for a particular drug, the process could produce inconsistent results and put companies and regulators in catch-22 situations. Some courts may conclude that a drug came to the market too quickly and hurt people unnecessarily. Public policy makers, including members of Congress, could find the same drug came to market too slowly to help those in need.²⁰⁶ Also, some courts could find that warnings were not strong enough, while others could find that there were too many warnings. This dichotomy will most likely arise where the perceived “injustice” of the side effect is greatest. One commentator notes:

The tort litigation system, unlike the administrative regulatory system, is generally unable to address the polycentric tradeoffs presented in regulation of upper-tier risks in the systematic manner that is required in order to strike a proper balance between risks and benefits. . . . For example, a decision not to approve a new drug because of its adverse side effects may deprive sick people of the therapeutic benefits that the drug would provide.²⁰⁷

A prescription drug system driven by strict liability concerns, therefore, would make it more difficult for physicians, who rely on prescription drugs and their warnings to be based on the most advanced scientific knowledge, to assess which drugs are most appropriate for particular patients.

B. Other Means to Achieve FDA Oversight and Compensation

Still, some support strict liability when prescription drug manufacturers follow FDA regulations. These individuals generally make two key points: (1) “[t]he tort system provides an important check on the regulatory process”,²⁰⁸ and (2) there is no “discussion concerning the need to offer redress for those who are injured” by prescription drugs.²⁰⁹ While the goals underlying these statements are important to consider, there are more appropriate and efficient mechanisms for achieving them than litigation.

NEWS MESSENGER, Apr. 19, 2004 (reporting that a woman shot her husband after she stopped taking her medication for schizophrenia).

206. See Richard A. Merrill, *The Architect of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1866 (1996) (observing that “[s]o long as FDA possesses final authority to determine which medical products get marketed, and on what terms, its performance will frequently disappoint, and often frustrate, manufacturers, patients, and members of Congress”).

207. Stewart, *supra* note 195, at 2174.

208. Gary Young, *FDA Strategy Would Preempt Tort Suits*, NAT’L L.J., Mar. 1, 2004, at 1, available at <http://www.law.com/jsp/nlj/PubArticleNLJ.jsp?id=1076428430132> (quoting Allison Zieve, an attorney with Public Citizen Litigation Group).

209. Dotson, *supra* note 117, at 47.

I. FDA Oversight

The American public has several direct checks on the FDA, including the President of the United States and the U.S. Congress, which have long histories of adjusting FDA authority and oversight to enhance safety and efficacy of prescription drugs.²¹⁰ The effectiveness of this oversight was seen most recently in the public reaction to the withdrawal of VIOXX from the market in autumn 2004 and the controversy over SSRIs (selective serotonin reuptake inhibitors) and their impact on children who suffer from depression. A congressional investigation and Executive Branch reassessment of VIOXX led to the creation of an independent auditing group to monitor after-market results of drug use.²¹¹ In addition, Pennsylvania Representative James Greenwood, who chairs the House Oversight and Investigations Committee, reacted to reports of suicidal tendencies from those taking SSRIs by demanding that four SSRI manufacturers turn over to the Congress some of their unpublished studies — the exact kind of information that plaintiffs' lawyers argue is only available through discovery.²¹² It may be worthwhile to note that these reforms occurred more quickly, uniformly, and in the public interest than would have been possible through litigation.

In addition, individuals can challenge the FDA's scientific judgments without the intervention of the President or Congress. Through filing Citizen's Petitions, the public can object to the FDA's approval of a drug and its labeling and ask the FDA to reconsider its findings.²¹³ If a Citizen's Petition

210. See *Current Issues Related to Medical Liability Reform: Hearing Before the Subcomm. on Health of the H. Energy and Commerce Comm.*, 109th Cong. 5 (2005) [hereinafter Schwartz Testimony] (statement of Victor E. Schwartz, General Counsel, American Tort Reform Association) (on file with authors) ("Not long ago, I remember when the FDA was challenged because it was not moving quickly enough in providing the American public with drugs that were needed to fight serious diseases. Now, among many, there is a contrary feeling — that the FDA may be moving too quickly and not carefully enough in the drug approval process. That debate is an important one to have in Congress, but it is not relevant for a core public policy decision about whether someone should be punished who has complied with the law."); see also William Safire, Editorial, *A World of Hurt*, N.Y. TIMES, Dec. 28, 2004, at A17 (writing in response to the VIOXX situation that, "people seeking relief have been afflicted by the overreaction to reports that several new pain alleviators, taken in large doses by especially vulnerable patients, may increase the risk of heart problems. . . . Rather than terrorize the F.D.A. into a cover-your-posterior paralysis, beef up its staff and expand the role of independent review panels to initiate as well as speedily review trials.").

211. See *supra* notes 72-80 and accompanying text.

212. See Young, *supra* note 208 (quoting Rep. Greenwood's letter as saying that "[s]ome doctors and advocates are concerned that the lack of publication of these studies distorts the scientific record").

213. 21 C.F.R. § 10.30 (2005); see, e.g., *Henley v. Food & Drug Admin.*, 77 F.3d 616 (2d

does not result in a satisfactory response, the petitioner can bring an Administrative Procedure Act proceeding against the agency to force reconsideration.²¹⁴

2. Compensation

Certainly, many individuals — including the authors of this article — may understand the desire to give compensation to those who experience a severe side effect, particularly when that side effect seems significantly disproportionate to a drug's benefit. But, taking that compensation through the tort system from a defendant who has complied with the law is not the sound public policy answer. Traditional principles of tort law would frown on this as well, as the law does not hold manufacturers responsible for insuring against all risks associated with a product.²¹⁵ Further, a consumer of prescription drugs implicitly accepts the bargained-for risk of experiencing a side effect. As discussed, the patient and her doctor make the decision of whether or not that risk trade-off is worth taking for a specific patient; the manufacturer does not have a role in this calculus.

Should a compensation system for victims of severe side effects be desirable, one can be created. Some legal observers have suggested that, if there were clarity in how the legal system handled these cases, private insurance companies could provide side effect insurance so that those who sustain debilitating injuries from prescription drugs could receive compensation.²¹⁶ Consumer-oriented insurance generally provides compensation much more accurately and economically than liability insurance,

Cir. 1996) (ruling on an appeal from a citizen's petition challenging the warning label for certain oral contraceptives).

214. Rein, *supra* note 34, at 3.

215. See James A. Henderson, Jr. & Aaron D. Twerski, *Closing the American Products Liability Frontier: The Rejection of Liability Without Defect*, 66 N.Y.U. L. REV. 1263, 1267 (1991) (“[D]efect is the conceptual linchpin that holds products liability law together; a system of liability without defect is beyond the capacity of courts to implement.”); Wade, *Strict Tort Liability*, *supra* note 125, at 828 (“Strict liability for products is clearly not that of an insurer. . . . Scope and extent of liability have usually been controlled by the concepts of proximate cause or risk . . .”).

216. 2 REPORTERS' STUDY, *supra* note 1, at 107 (suggesting that a “national system of insurance for victims of prescription drug side-effects” would supplant the need for compensation through liability). As with all types of insurance, side effect insurance could efficiently spread loss experienced by the few among the many users of prescription drugs. Stewart, *supra* note 195, at 2182 (recommending a “no-fault compensation system for those injured by products or processes that have previously been approved by regulators as socially net-beneficial. For example, a system might be established to cover the economic losses incurred by those injured by the side effects of FDA-approved drugs.”).

which is expensive and has high transactional costs.²¹⁷ The sense, however, is that as long as courts inconsistently approach prescription drug liability, the marketplace probably will not provide such solutions.

When this problem arose with the predictable, specific, and known risks associated with childhood vaccines, Congress recognized that there were special circumstances for childhood vaccines and established a compensation fund.²¹⁸ While the compensation fund mechanism may not be appropriate where the risks are unknown or not predictable, the developments in litigation surrounding childhood vaccinations illustrate the public policy issues at play in this article.²¹⁹ Between the mid-1960s and early 1980s, cases involving debilitating injuries to children ostensibly caused by the vaccines generated “seriously erroneous and inconsistent liability decisions.”²²⁰ In many cases, these verdicts were “directly contrary to regulatory determinations regarding product risks and benefits,” as well as accepted scientific principles.²²¹ Nevertheless, the claims amounted to more than \$3.5 billion between 1980 and 1986,²²² leading more than half of all commercial vaccine manufacturers to stop producing vaccines.²²³ Vaccine prices rose precipitously, stockpiles of the

217. Victor E. Schwartz, *Tort Law Reform: Strict Liability and the Collateral Source Rule Do Not Mix*, 39 VAND. L. REV. 569, 573-74 (1986).

218. Vaccines protect children from debilitating and deadly diseases such as polio, measles, whooping cough, rubella, tetanus, influenza, mumps, hepatitis, pneumococcal and meningococcal infections, diphtheria, and smallpox. See COMM. ON THE EVALUATION OF VACCINE PURCHASE FINANCING IN THE UNITED STATES, BD. ON HEALTH CARE SERVS., INST. OF MEDICINE, FINANCING VACCINES IN THE 21ST CENTURY 24 (2004) [hereinafter FINANCING VACCINES IN THE 21ST CENTURY] (providing statistics on the change in annual morbidity from vaccine-preventable diseases); 42 U.S.C. §§ 300aa-10 to 300aa-17 (2000). A small percentage of those children may have a negative reaction to a vaccine and sustain serious injury. Nevertheless, many states require every child to be vaccinated from these and other potential diseases in order to attend public school. See FINANCING VACCINES IN THE 21ST CENTURY, *supra*, at 27-29, 42-44; Victor E. Schwartz & Liberty Mahshagian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 393-94 (1987).

219. See *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659 (S.D. Tex. 2004) (“Congress has established a comprehensive regulatory scheme, administered by the FDA, to control the design and distribution of prescription drugs, including vaccines.”).

220. Stewart, *supra* note 195, at 2171.

221. *Id.*

222. See Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL., POL’Y & L. 59, 60-61 (1999).

223. See FINANCING VACCINES IN THE 21ST CENTURY, *supra* note 218, at 121-22. Vaccines are injected into healthy children as a means of preventing infection or disease. On rare occasions, vaccines lead to serious side effects. See Centers for Disease Control and Prevention, *Vaccine Side Effects*, at <http://www.cdc.gov/nip/vacsafe/concerns/side-effects.htm> (last visited Oct. 24, 2005). Parents also blame vaccines for other ailments their children may derive after being vaccinated. For example, while scientific studies suggest otherwise,

vaccines dropped to dangerous levels, and often only a single manufacturer produced each of several childhood vaccines.²²⁴ Many feared that the country was on the brink of a public health hazard.²²⁵

Led by California Representative Henry Waxman, Congress created the National Vaccine Injury Compensation Program (VICP),²²⁶ a no-fault fund to compensate those who experienced negative side effects from childhood vaccines.²²⁷ Claimants could recover medical expenses, reasonable attorney's fees, and up to \$250,000 for pain and suffering.²²⁸ As indicated, this approach can only work for very specific, named, and predictable risks.²²⁹

A claimant not wanting to be limited by the fund's compensation

numerous parents blame their children's autism on the mercury preservative used in some vaccines. *See* Thomas H. Maugh II, *New Autism Cases Level Off in State, Data Show*, L.A. TIMES, July 12, 2005, at B6. As a result, damages in childhood vaccine suits can be significantly high. Schwartz & Mahshigian, *supra* note 218, at 388 (noting that there is an unavoidable risk that the Sabin Polio vaccine can in rare cases cause the recipient and persons coming in contact with the recipient to develop polio).

224. *See* Ridgway, *supra* note 222, at 61; H.R. REP. NO. 99-908, at 4-5 (1986), *reprinted in* 1986 U.S.C.C.A.N. (100 Stat. 3743) 6344, 6345.

225. *See* H.R. REP. NO. 99-908, at 7, *reprinted in* 1986 U.S.C.C.A.N. 6348.

226. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 to 300aa-17 (2000). In enacting the Vaccine Act in 1986, Congress met two basic concerns: "the inadequacy — from both the perspective of vaccine-injured persons as well as vaccine manufacturers — of the current approach to compensating those who have been damaged by a vaccine; and . . . the instability and unpredictability of the childhood vaccine market." H.R. REP. NO. 99-908, at 7, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348.

227. Individuals who seek to recover more than \$1000 or an unspecified amount for injuries allegedly due to childhood vaccines must file a claim in the Federal Court of Claims to be adjudicated by a special master. *See* 42 U.S.C. § 300aa-11(a)(2)(A). The government is the defendant in this proceeding, rather than the vaccine manufacturers. *See id.* § 300aa-12(b). Damages are paid for by a fund created by a tax on all vaccines. *See* 26 U.S.C. § 9510 (2000).

228. *See* 42 U.S.C. § 300aa-15(a). Congress also prohibited claims for punitive damages. As the Committee Report for the Vaccine Act recognized,

punitive damages should be assessed only where particularly reprehensible, conscious behavior is involved. Where a manufacturer has attempted in good faith to comply with a government standard — even if the standard provides inadequate protection to the public — the manufacturer should not be assessed punitive damages absent evidence that it engaged in reprehensible behavior that directly resulted in the establishment of maintenance of the standard's inadequacy.

H.R. REP. NO. 99-908, at 28-29, *reprinted in* 1986 U.S.C.C.A.N. 6369, 6370.

229. *See* Stewart, *supra* note 195, at 2172 (stating that there is concern that liability is inhibiting the development of certain drugs and adult vaccines, such as a vaccine for AIDS); *see also* Jon Cohen, *Is Liability Slowing AIDS Vaccines?*, SCIENCE, Apr. 10, 1992, at 168, 168 ("Some pharmaceutical companies and biotech companies, concerned about potential damage suits, are taking a tentative approach to the development of an AIDS vaccine.").

mechanism could still seek judicial action.²³⁰ In concert with the legal theories discussed in this article, Congress clarified that in litigation, a vaccine manufacturer would not face liability for any unavoidable side effects where the manufacturer properly prepared the vaccine and included proper directions and warnings as determined by the FDA.²³¹ Since this legislation was enacted, childhood immunization has increased, supplies have remained stable, and wholesale prices have decreased.²³²

VI. How Courts Should Handle Prescription Drug Litigation

As this article demonstrates, when litigation arises out of side effects from prescription drugs, courts should allow the FDA to establish the standard of care for design and warning defect and focus the litigation on areas not

230. See 42 U.S.C. § 300aa-21(a).

231. See *id.* §§ 300aa-22(a)(2), 300aa-22(b); H.R. REP. NO. 99-908, at 25-26, reprinted in 1986 U.S.C.C.A.N. 6368, 6369. The only cases appropriate for the courts were where a manufacturer faced charges of fraud, misrepresentation, or other illegal activity concerning the safety of the vaccine, or allegations that the manufacturer failed to exercise due care. See §§ 42 U.S.C. 300aa-22(a)(2), 300aa-23(d)(2).

232. See Ridgway, *supra* note 222, at 76-77. Recently, plaintiffs' lawyers have sought to circumvent the VICP. For example, plaintiffs' lawyers have argued that thimerosal, a preservative included in many vaccines, is an "adulterant" or "contaminant." They argue that for this reason claims alleging harm from thimerosal are excluded specifically by the Vaccine Act's definition of "vaccine-related injury." 42 U.S.C. § 300aa-33(5). Most courts have rejected such claims. As one court said, "every federal court to have ruled on the issue has held that injuries resulting from Thimerosal contained in vaccines are vaccine-related under the meaning of the Act." *Bertrand v. Aventis Pasteur Labs., Inc.*, 226 F. Supp. 2d 1206, 1213 (D. Ariz. 2002). Still, the four manufacturers of children's vaccines, as well as pediatricians and other health care providers, are facing about 190 individual and class action lawsuits in state and federal courts with "millions of plaintiffs alleging potential thimerosal-related injuries." See Letter from Elizabeth J. Noyes, Chair of the Advisory Commission on Childhood Vaccines, to Tommy G. Thompson, Secretary of Health and Human Services (Dec. 6, 2002) (on file with author). The lawsuits allege that the preservative in childhood vaccines causes such health disorders as autism, attention deficit disorders, and learning disorders. See *id.* The huge potential liability exposure and defense fees in these cases can crush companies. See U.S. GEN. ACCOUNTING OFFICE, CHILDHOOD VACCINES: ENSURING AN ADEQUATE SUPPLY POSES CONTINUING CHALLENGES(GAO-02-987) 24-25 (Sept. 2002) (discussing liability concerns and defense costs as factors leading to vaccine shortages).

governed by exacting FDA regulations.²³³ The court has two mechanisms for doing so: federal preemption and the regulatory compliance defense.²³⁴

A. Preemption

Under the Supremacy Clause of the U.S. Constitution,²³⁵ federal law or regulatory regimes can displace — or “preempt” — state legislative, regulatory, or judicial decisions.²³⁶ When a federal law includes an express preemption provision, it has priority over conflicting state laws. When such a preemption provision does not exist, states generally can assume that federal law does not preempt state law. But, according to the United States Supreme Court, the assumption of “nonpre-emption is not triggered . . . where there has been a history of significant federal presence.”²³⁷

The FDA’s enabling statutes do not include an express preemption provision for prescription drugs.²³⁸ Therefore, courts would have to consider whether the FDA’s regulatory regime impliedly preempts state tort law.²³⁹ The first consideration is whether the FDA regulatory regime is so pervasive that it “occupies the field” such that state-by-state actions would frustrate “the full purposes and objectives” of the FDA’s mandate.²⁴⁰ The *Reporters’ Study* has observed that where the “Federal standard sets the optimal balance, then state laws that diverge from it — either to relax or tighten regulations — are in

233. Some reports note that the FDA’s regulatory oversight, particularly with respect to direct-to-consumer advertising, has been limited due to resource constraints and changes in the Department of Health and Human Services’ policy for review that serves to lengthen review time, often beyond the effective period. See U.S. GEN. ACCOUNTING OFFICE, *PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS* (GAO-03-177) (Oct. 2002).

234. See generally Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147 (2000) (distinguishing an FDA compliance defense from federal preemption); Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461 (1997) (discussing the merits of the regulatory compliance defense).

235. See U.S. CONST. art. VI, cl. 2.

236. See *id.* See generally Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085 (2000) (discussing the various considerations for reviewing the preemptive nature of federal regulation).

237. *United States v. Locke*, 529 U.S. 89, 108 (2000).

238. See Richard C. Ausness, *The Case for a “Strong” Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1232 (1996) [hereinafter Ausness, “Strong” Regulatory Compliance].

239. M. Stuart Madden, *Federal Preemption of Inconsistent State Safety Obligations*, 21 PACE L. REV. 103, 140-41 (2000) (observing that the FDA has accepted its role in establishing national standards for marketing and manufacturing prescription drugs and has approached its regulation and enforcement responsibilities accordingly).

240. *Medtronic v. Lohr*, 518 U.S. 470, 496 (1996).

‘conflict’ with the ‘federal purpose’ and therefore preempted.’²⁴¹ Also, consideration should be given to whether separate risk-benefit analyses in each jurisdiction for each prescription drug would undermine a national uniform regulatory regime.²⁴² Where courts determine that there is “no room” left for state action, FDA regulations preempt tort law.²⁴³

Implied preemption also occurs when state tort law is in actual conflict with an FDA regulation²⁴⁴ — an argument the FDA has made in several recent *amicus curiae* briefs.²⁴⁵ In *Motus v. Pfizer, Inc.*, for example, the FDA stated that “state law may require the manufacturer of a drug to warn of a specific danger that the FDA, based on scientific analysis, concludes does not exist.”²⁴⁶ The problem, as explained by the FDA, is that if a prescription drug manufacturer were to abide by such state law, the FDA would consider the drug “misbranded” and conduct enforcement actions against the manufacturer. Thus, a drug manufacturer could not abide by both the “regulation” imposed by the state court through liability and the regulations issued by the FDA.²⁴⁷

The Supreme Court of California agreed with the FDA in *Dowhal v. SmithKline Beecham Consumer Healthcare*,²⁴⁸ a 2004 decision striking down a state-required warning for pregnant women pertaining to all products containing nicotine, including those that help people stop smoking.²⁴⁹ The court observed that the case presented a “complex labeling issue because . . . the purpose of the products is to help individuals stop smoking, and smoking

241. 2 REPORTERS’ STUDY, *supra* note 1, at 108.

242. *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992) (stating that state action cannot stand “as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress”) (citations omitted). The FDA has argued that Congress made the FDA the gatekeeper to decide which warnings are “scientifically substantiated.” FDA Brief, *supra* note 189, at 4-5, 23.

243. *See Pennsylvania v. Nelson*, 350 U.S. 497, 504 (1956).

244. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 899 (2000).

245. *See, e.g., Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984 (C.D. Cal. 2001), *aff’d*, 358 F.3d 659 (9th Cir. 2004); *see also* James Dabney Miller, *FDA Should Propose Rule on Federal Preemption of Failure-to-Warn Lawsuits*, LEGAL BACKGROUNDER (Wash. Legal Found.), Sept. 19, 2003, at 5, available at <http://www.wlf.org/Publishing/pubsbyyear.asp?year=2003> (suggesting that “[i]n light of [the FDA’s] *amicus* position in *Motus* that the FDCA preempts all or at least some failure-to-warn claims, FDA should begin a notice-and-comment rulemaking on a proposed regulation that would set out the precise boundaries of state-law failure-to-warn claims that are preempted”).

246. FDA Brief, *supra* note 189, at 16; *see also Hurley v. Lederle Labs.*, 863 F.2d 1173, 1179 (5th Cir. 1988) (“[A]ssuming that the FDA has processed all the relevant and available information in arriving at the prescribed warning, its decision as to the proper wording must preempt by implication that of a state.”)

247. *See Miller*, *supra* note 245, at 3.

248. 88 P.3d 1 (Cal. 2004).

249. *See id.* at 3.

is even more dangerous to the fetus.”²⁵⁰ The FDA label should prevail, the court said, because it represented “an effort to balance these competing concerns.”²⁵¹ While the anti-smoking products were available without a prescription, the same principles apply to prescription drugs.

B. Judicial Regulatory Compliance Defense

The regulatory compliance defense is the flip-side of preemption, as the authority rests with the states, rather than the federal government.²⁵² Under the regulatory compliance defense, courts use their own authority to establish a common law deference to the FDA’s regulatory scheme for prescription drugs.²⁵³ As discussed earlier in this article, several state high courts, such as those in California, Washington and Utah, have adopted, as a practical matter, a regulatory compliance defense for prescription drugs.²⁵⁴

In these jurisdictions, a prescription drug manufacturer does not face strict liability for design defect or failure to warn when it has met the FDA duty of care for reasonable research, instructions, and warnings.²⁵⁵ Thus, to be eligible for this protection, a company must have disclosed to the FDA all material information in its possession relating to hazards or safe use.²⁵⁶

[This] disclosure condition serves to enlist the energies of plaintiffs’ lawyers in ferreting out instances of firms’ nondisclosure, so that plaintiffs can proceed with tort claims. . . . It may be even more effective than the current tort system in accomplishing this goal because it makes detection and revelation of nondisclosure a precondition for maintaining a tort claim.²⁵⁷

As the *Reporters’ Study* observed more than a decade ago, the prescription drug market presents the “special combination of circumstances justifying” a

250. *Id.* at 4.

251. *Id.* at 5. “[T]he FDA has authority to prohibit truthful statements on a product label if they are ‘misleading’ or if they are not stated in ‘such manner and form, as are necessary for the protection of users.’” *Id.* at 12 (citations omitted). *But see* Bell v. Lollar, 791 N.E.2d 849 (Ind. Ct. App. 2003) (holding that a state law failure to warn claim was not preempted by FDA regulations).

252. *See generally* Ausness, “Strong” Regulatory Compliance, *supra* note 238.

253. *See id.*

254. *See, e.g.,* Brown v. Superior Court, 751 P.2d 470 (Cal. 1988) (the court deferred to the FDA to regulate the prescription drug market in the absence of state tort liability); Grundberg v. Upjohn Co., 813 P.2d 89 (Utah 1991) (deferring to the FDA regulatory regime instead of subjecting prescription drug manufacturers to state tort liability).

255. *See Grundberg*, 813 P.2d at 90.

256. *See* Stewart, *supra* note 195, at 2180-81.

257. *Id.*

regulatory compliance defense: (1) public health benefits depend heavily on innovation; (2) the regulatory regime “carefully balances” risk and benefit per product; (3) inherent harms that cannot be prevented through liability or regulation; (4) the regulatory controls are part of a detailed regime; (5) the regulations demand pervasive reporting requirements; (6) there already exists a strong market incentive to generate safe products; and (7) the activity is sale of uniform, national products.²⁵⁸

C. Legislative Regulatory Compliance Defense

Several state legislatures have used their state’s authority to codify a regulatory compliance defense for prescription drugs.²⁵⁹ In Michigan, the legislature specifically yielded to FDA regulations for establishing tort liability for prescription drugs.²⁶⁰ Other states, including Arizona, New Jersey, Ohio, Oregon, and Utah have limited liability for punitive damages when manufacturers complied with FDA regulations.²⁶¹ In addition, states such as Colorado, Indiana, Kansas, Kentucky, Tennessee, and Utah have enacted laws providing that compliance with federal or state government safety regulations — for all products, not just prescription drugs — creates a rebuttable presumption that a product is not defective.²⁶²

258. 2 REPORTERS’ STUDY, *supra* note 1, at 103-04 (concluding generally that where serious risks are involved and the pharmaceutical is needed to treat a major illness, the “advantages of consistent regulation over case by case litigation are likely to be greatest”).

259. *See, e.g.*, MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000) (“In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration’s approval at the time the drug left the control of the manufacturer or seller.”); TENN. CODE ANN. § 29-28-104 (2004) (“Compliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions for use of a product, shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards.”).

260. *See, e.g.*, MICH. COMP. LAWS ANN. § 600.2946(5); *see also* Taylor v. Smithkline Beecham Corp., 658 N.W.2d 127, 131 (Mich. 2003) (upholding the state constitutionality of codifying of a law stating that “a manufacturer or seller of a drug that has been approved by the FDA has an absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA’s approval at the time the drug left control of the manufacturer or seller”).

261. ARIZ. REV. STAT. ANN. § 12-701(A) (2002); N.J. STAT. ANN. § 2A:58C-4, 5(c) (West 1985 & Supp. 2005); OHIO REV. CODE ANN. § 2307.80 (LexisNexis 2004); OR. REV. ST. § 30.927 (2003); UTAH CODE ANN. § 78-18-2(1) (2002).

262. *See* COLO. REV. STAT. § 13-21-403(1) (2004); IND. CODE ANN. § 34-20-5-1 (LexisNexis 2004); KAN. STAT. ANN. § 60-3304(a) (1995 & Supp. 2004); KY. REV. STAT. ANN. § 411.310(2)

When the law in Ohio was enacted in 1987, those who opposed it predicted that the drug companies might treat Ohio as part of “Sodom and Gomorra” by dumping dangerous or defective drugs in the state and dropping damaging warnings from their packaging.²⁶³ There have been no reports of that happening. In fact, in 2005 the Ohio legislature expanded coverage of the statute and banned punitive damages for FDA-compliant manufacturers of over-the-counter drugs and medical devices, in addition to prescription drugs.²⁶⁴

VII. The Causation Requirement

Should a case proceed — whether preemption or regulatory compliance was not appropriate or because some other legal reason prevailed — the court should take steps to minimize the opportunity for bad science to undermine both the tort system and the FDA’s ability to set risk strategy for individual prescription drugs. The best way to do this would be to make determinations on both general and specific causation early in the litigation.

Courts first must determine whether the drug in question does cause the alleged harm. For example, the controversy over the effect of SSRIs on children centers on whether the SSRIs actually caused the children to commit suicide or whether the children committed suicide because of the underlying state of depression.²⁶⁵ In reaching this decision, courts may be guided by reports from experts on epidemiological and placebo controlled tests and whether there is a “signature” disease that a drug is alleged to cause.²⁶⁶ Where the ailment is common to mankind, such as heart disease or cancer, courts should tread very carefully.²⁶⁷ Courts must conclusively resolve any

(West 2004); TENN. CODE ANN. § 29-28-104; UTAH CODE ANN. § 78-15-6(3).

263. See Schwartz Testimony, *supra* note 210, at 7.

264. 2005 Ohio Laws File 144 (Am. Sub. S.B. 80) (amending OHIO REV. CODE ANN. § 2307.80) (effective Apr. 7, 2005).

265. See *Fiscal Year 2006 Hearing on Substance Abuse and Mental Health Research Services: Hearing Before the Subcomm. on Labor, Health and Human Servs., and Educ of the H. Comm. on Appropriations*, 109th Cong. (2005) (statement of Dr. Thomas R. Insel, Director, Nat’l Inst. of Mental Health), available at 2005 WL 996064 (discussing the risks of suicide among children for depression generally as well as the debate over whether SSRIs “can actually increase suicidal thinking”).

266. See generally MICHAEL D. GREEN ET AL., FED. JUDICIAL CTR., REFERENCE GUIDE ON EPIDEMIOLOGY, at [http://www.fjc.gov/public/pdf.nsf/lookup/sciman06.pdf/\\$file/sciman06.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/sciman06.pdf/$file/sciman06.pdf) (last visited Aug. 1, 2005).

267. See Laura Vozzella & Ivan Penn, *Lining Up Suits Against Painkillers*, BALTIMORE SUN, Dec. 23, 2004, at 1A (reporting on VIOXX litigation and stating that “the anticipated flurry of lawsuits doesn’t mean the cases will be slam-dunks. Some personal injury lawyers concede that the suits will be difficult because heart attacks and strokes — the problems blamed on the

uncertainty before specific causation can be raised. The key issue for specific causation is whether a drug caused an injury or whether the ingestion of the drug simply happened before the onset of an illness.

VIII. Conclusion

All prescription drugs are unavoidably dangerous to some of their users. In light of that scientific fact, public policy oriented courts have exempted prescription drugs from strict liability for design and failure to warn defects. The result is a fault-based system.

Because the FDA uses a highly scientific and deliberative process to approve each drug and all warnings, the FDA is entitled to deference in the tort system. If the FDA process is flawed, it is the responsibility of Congress and the Executive Branch, which can view the total picture of the pharmaceutical regulatory process, to make changes. When public health events have exposed weaknesses in the system in the past, the President and Congress have expanded the FDA's authority, provided the FDA with more resources to fix problems, and enhanced independent oversight of the FDA's work.

When each court creates different rules for prescription drug liability, the justice system fails; the public's interest in having a stable system for prescription drugs is undermined by unpredictable and sometimes inaccurate legal outcomes. Such a decentralized approach does make sense for resolving private conflicts, but with the national prescription drug market, there is "a likelihood of erroneous and inconsistent risk-benefit decisions, uncertainty, and a threat of overdeterrence of socially beneficial products."²⁶⁸

This problem becomes most vivid for "upper-tier" risks posed by potent drugs that come with significant or frequent side effects, but can alleviate harmful and potentially life-threatening situations. While this approach may result in some individuals not receiving compensation through the tort system, the same is true for many other serious risks in society. The tort system is not a compensation system. If a compensation system is needed for prescription drugs, policy makers should give that issue a hearing. But, that attention will never be obtained if courts allow a roulette system to prevail in pharmaceutical liability.

drugs — are common afflictions with many causes.”).

268. Stewart, *supra* note 195, at 2169.